Registration No 524-595 Vol. 1

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: 12/22/09		EPA Reg. Number: 524-LOL		
	Check List Item	Yes	No	N/A
1	Has the **PRIA Fee been Paid**; is a copy of the check or Pay.gov receipt included in the Submission Package?	✓		
2	Is an **Application Form** (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	✓		
3	Is a **Confidential Statement of Formula** (EPA Form 8570-29) included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	✓		
4	Is a **Formulator's Exemption Statement** (EPA Form 8570-27) Included in the Submission Package?		✓	
5	Is a **Certification with Respect to Citation of Data** (EPA Form 8570-34) Included in the Submission Package?	✓		
6	Is a **Data Matrix** (EPA Form 8570-35) Included in the Submission Package?	✓		
7	Is a **Label** Included in the Submission Package?	✓		
8	Are **Data** Included in the Submission Package?	✓		
9	**Is the Submission an Amendment?**		✓	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NOV 22 2011

Dr. J. Austin Burns
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63137

Subject: MON 89034 x TC1507 x MON 88017 x DAS-59122-7 and MON 89034 x TC1507 x MON 88017 x DAS-59122-7 RIB Complete™ June 10, 2011 and October 27, 2011 Applications to Amend the Expiration Date for Monsanto SmartStax Products
EPA Registration Nos. 524-581 and 524-595

Dear Dr. Burns:

The amendments referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable subject to the following terms and conditions.

1) The expiration date for these products is November 30, 2013.

2) The Agency recognizes that large corn rootworm populations, environmental conditions, and protein expression levels can influence corn root damage and may affect the definition of suspected CRW resistance. The Agency plans to work with the registrants to refine the definition of suspected resistance based on these factors. Until such time that the Agency accepts a modified definition of suspected resistance to corn rootworm, resistance will be suspected in cases where the average root damage in the SmartStax field is > 0.5 on the nodal injury scale (NIS) and the frequency of SmartStax with > 0.5 nodes destroyed exceeds 50% of the sampled plants.

3) Within 90 days of this amendment, you must submit an enhanced rootworm resistance monitoring plan for SmartStax that accounts for reports of suspected and/or confirmed resistance. The rootworm resistance monitoring plan and the revised definitions for suspected and confirmed resistance for SmartStax must be found acceptable to BPPD by May 1, 2012 and utilized by Monsanto beginning in the 2012 season. This enhanced monitoring program should:

- o Be practical and adaptable and provide information on relevant changes in corn rootworm population sensitivity to SmartStax;

- o Be focused on areas where the potential for resistance is greatest for SmartStax and for the corn rootworm active single event components of SmartStax (Cry3Bb1and Cry34Ab1/Cry35Ab1), based on available information on historical pest pressure, unexpected performance issues, historical suspected and/or confirmed resistance incidents as currently defined or as modified in EPA accepted enhanced monitoring programs, prevailing agronomic practices (e.g. crop rotation versus continuous corn), and academic and extension publications on Bt corn field performance;

- o Involve coordination to the extent possible with other stakeholders, such as academic and extension experts in the states where corn rootworm is a major pest, other registrants of SmartStax, and other registrants of similar products, as appropriate;

- o Be responsive to incidents of suspected or confirmed resistance to the registrant's other products containing the same active ingredient(s), as well as to publicly available reports of suspected or confirmed resistance to other *Bt* protein toxins in SmartStax.

4) Within 90 days of this amendment, you must submit an enhanced remedial action plan for SmartStax that includes actions to be taken in response to both suspected and confirmed resistance. This remedial action plan must include a description of steps to be taken in response to customer product performance inquiries and annual reporting to the agency on the outcomes of investigations into any such inquiries that might indicate potential resistance. The program must include revised definitions of unexpected damage to SmartStax corn that could indicate potential suspected resistance. The enhanced remedial action plan must be found acceptable to BPPD by May 1, 2012.

5) The Grower Guide or its supplements must include language directing the user to contact a company representative if they observe unexpected insect feeding damage to their SmartStax corn. As part of its follow up on reports of unexpected damage to SmartStax corn, the registrant must determine the nodal injury scale (NIS) of affected corn. If the NIS results fall within the definition of suspected resistance for SmartStax, then until such time as the Agency accepts a modified remedial action plan, the registrant must provide specific guidance to affected growers in managing corn rootworms in the affected fields. This will include 1) providing specific grower guidance to control the adult stage of corn rootworms, where adult beetles are still present and

laying eggs during the season that unexpected damage meets the suspected resistance definition; and 2) where the grower continues to be an existing customer of the registrant or seed company licensee into the following season, providing specific grower guidance and assistance to use an additional or alternative pest control method during the season following the initial finding that unexpected damage meets the suspected resistance definition.

6) Monsanto will submit additional modeling, scientific literature, and other scientific information addressing the impact of pyramid PIP use in areas of confirmed resistance to one of the rootworm-active components of the pyramid by August 30, 2012.

7) Should resistance to any of the constituent toxins of SmartStax be confirmed (from target pest populations collected in 2012 or prior growing seasons) in accordance with the existing definition of "confirmed resistance" for the appropriate toxin, EPA will reassess and, if EPA concludes it is necessary, Monsanto will revise the refuge/seed blend requirements for SmartStax. The registrants may independently submit updated definitions of confirmed resistance for their respective SmartStax active proteins for EPA's consideration in order to harmonize and/or keep definitions current with scientific standards; any such submission must be found acceptable to BPPD by May 1, 2012. EPA will incorporate all relevant scientific information (including the data required above) in its reassessment of the refuge/seed blend requirements. The revised refuge/seed blend requirements will be effective for the following growing season (after resistance confirmation) in the geographic areas in which resistance was confirmed. The geographic area of confirmed resistance could be less than a single county, a single county, or multiple counties, depending on EPA's analysis of the collected data.

8) For the SmartStax block refuge products, submit a revised Compliance Assurance plan by February 28, 2012.

Sincerely,

Keith A. Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NOV 22 2011

Dr. J. Austin Burns
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63137

Subject: MON 89034 x TC1507 x MON 88017 x DAS-59122-7 and MON 89034 x TC1507 x MON 88017 x DAS-59122-7 RIB Complete™ June 10, 2011 and October 27, 2011 Applications to Amend the Expiration Date for Monsanto SmartStax Products EPA Registration Nos. 524-581 and 524-595

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CONCURRENCES							
SYMBOL	75111	7511P	25110				
SURNAME							
DATE	11/22/11	11/22/11	22 NOV 11				

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- o Be focused on areas where the potential for resistance is greatest for SmartStax and for the corn rootworm active single event components of SmartStax (Cry3Bb1and Cry34Ab1/Cry35Ab1), based on available information on historical pest pressure, unexpected performance issues, historical suspected and/or confirmed resistance incidents as currently defined or as modified in EPA accepted enhanced monitoring programs, prevailing agronomic practices (e.g. crop rotation versus continuous corn), and academic and extension publications on Bt corn field performance;

- o Involve coordination to the extent possible with other stakeholders, such as academic and extension experts in the states where corn rootworm is a major pest, other registrants of SmartStax, and other registrants of similar products, as appropriate;

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8) For the SmartStax block refuge products, submit a revised Compliance Assurance plan by February 28, 2012.

Sincerely,

Keith A. Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 27 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dr. J. Austin Burns
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63137

Subject: MON 89034 x TC1507 x MON 88017 x DAS-59122-7 RIB Complete™
June 10, 2011 Application to Amend the Expiration Date
EPA Registration No. 524-595

Dear Dr. Burns:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that the revised expiration date for this product is November 30, 2011. Per our discussions with Monsanto, the Agency intends to determine a longer term expiration date for this product, along with other SmartStax related products, during the month of November. In order to facilitate this process, please submit a corresponding amendment application.

Sincerely,

Sheryl K. Reilly, Ph.D.
Chief, Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 27 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dr. J. Austin Burns
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63137

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Sincerely,

Sheryl K. Reilly, Ph.D.
Chief, Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CONCURRENCES								
SYMBOL ▶		7511P						
SURNAME ▶	7511P							
DATE ▶	10/27/11	10/27/11						

MONSANTO
imagine

J. Austin Burns
Regulatory Affairs Manager
(314) 694-6514

MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ST. LOUIS, MISSOURI 63167
http://www.monsanto.com

October 27, 2011

Document Processing Desk (PETN)
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application to extend the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™; EPA Registration Number 524-595; non-PRIA

Dear Dr. Reilly:

Please find an application for the registration extension of the plant-incorporated protectant MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete Insect Protected, Herbicide-Tolerant Corn (EPA Reg. No. 524-595) enclosed.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ was conditionally registered on April 8, 2011. The initial time-limited registration expired on October 31, 2011, which was subsequently extended to November 30, 2011 (EPA letter, October 27, 2011).

During the initial registration period, Monsanto, in conjunction with Dow AgroSciences (EPA Reg. No. 68467-16), provided further information supporting this product in accordance with the terms and conditions of registration, including an updated draft label. This current application request is to extend EPA Reg. No. 524-595 for a period of two years beyond the current November, 30, 2011 expiration date based on the EPA's registration decision in the BRAD for this product (EPA Docket ID EPA-HQ-OPP-2011-0362-0002, April 8, 2011; p27). A subsequent registration extension will be requested at that time, based on the revised registration duration scheme for PIP products representing reduced risk for developing insect resistance (Optimum® AcreMax™ B.t. Corn Seed Blends BRAD; August 4, 2010; p19).

Pursuant to this request, attached is a letter from Dow AgroSciences authorizing data citation related to Events TC1507 and DAS-59122-7.

The documents accompanying this submission are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.

- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

- Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

An email containing the fully releasable ("A") documents, with the exception of the data citation authorization letter, is being provided separately.

It is Monsanto's understanding that this request is a non-PRIA action.

- Fee category: Non-PRIA Amendment
- Fee category amount: $0

Should you require any additional information regarding this application please feel free to contact Daniel Jenkins at 202-383-2851, or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.
Regulatory Affairs Manager
Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD
Dan Jenkins, Monsanto

Documents accompanying this application

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√	√
N/A	A	Dow AgroSciences data citation letter	√	
N/A	A	Transmittal document	√	√
1	A	CBI-Deleted version: Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture		√
1	B	Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture	√	
1	C	Confidential Statement of Formula	√	

Dow AgroSciences, LLC
9330 Zionsville Road
Indianapolis, IN 46268-1054

Dow AgroSciences

May 27, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Keith Matthews, Esq., Director Biopesticide and Pollution Prevention Division

LETTER AUTHORIZING DATA CITATION

We hereby confirm that Agrigenetics, Inc. d/b/a Mycogen Seeds c/o Dow AgroSciences LLC, on behalf of itself and its affiliates, (collectively, "Dow AgroSciences") authorizes Monsanto Company (Monsanto) to cite, and the U.S. Environmental Protection Agency (EPA) to refer to, data previously submitted by Dow AgroSciences in connection with any of the following products:

- *Insect-protected, glufosinate-tolerant maize containing the Cry1F and PAT proteins, Event TC1507 (DAS-01507-1);*
- *Insect-protected, glufosinate-tolerant maize containing the Cry34/35Ab1 and PAT proteins, Event DAS-59122-7 (DAS-59122-7)*

and all relevant data that Dow AgroSciences has provided EPA to support the Section 3 registration extension for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Insect-Protected, Herbicide-Tolerant Corn (Refuge Advanced™ Powered by SmartStax® / Genuity® SmartStax® RIB Complete™), EPA Registration Nos. 68467-16 and 524-595.

This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any application submitted by any other applicant, for an application by Monsanto for activities other than the registration request as described herein, or for any other regulatory entity to refer to or rely on this data. Dow AgroSciences does not grant permission for citation or reference of this data for any use not specifically stated herein, does not grant permission for citation or reference of data (including future data) not specified herein, and nothing in this agreement grants permission for the U.S. EPA to provide copies of any data to any party.

If you require further information, please contact the undersigned at 317-337-3692.

Best Regards,

Gregory L. Orr, Ph.D.
Global Regulatory Leader – Corn Traits
Dow AgroSciences LLC

SmartStax® multi-event technology developed by Dow AgroSciences and Monsanto.
®SmartStax is a registered trademark of Monsanto Technology LLC.

MONSANTO

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

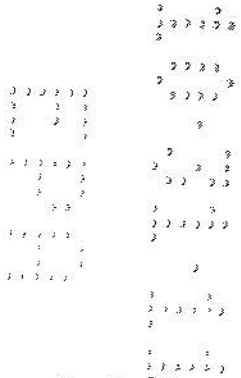
EPA Registration Number: 524-595

TRANSMITTAL DATE

October 27, 2011

MONSANTO REFERENCE No.

11-CR-192E-2R



LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1. Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

MRID Number _____

Company Official: _____ 10-27-2011
J. Austin Burns, Ph.D. Date
Regulatory Affairs Manager
(314) 694-6514

Company Name: Monsanto Company

Company Contact: Daniel Jenkins, J.D., M.S.
U.S. Agency Regulatory Affairs Manager
(202) 383-2851

MONSANTO

VOLUME 1

Administrative Materials for the Application to Amend the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Reg. Number: 524-595

AUTHORS

Bradley A. Comstock
J. Austin Burns, Ph.D.

SUBMISSION DATE

October 27, 2011

SUBMITTING REGISTRANT

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

MONSANTO REFERENCE No.

11-CR-192E-2R

The text below applies only to use of the data by the United States Environmental Protection Agency (U.S. EPA) in connection with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

STATEMENT OF DATA CONFIDENTIALITY CLAIM

No claim of data confidentiality is being made for information contained in this document on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). However, a supplemental data confidentiality claim is being made for some information claimed herein. The applicable information has been removed to a confidential attachment.

"We submit this material to the United States Environmental Protection Agency specifically under requirements set forth in FIFRA as amended, and consent to use and disclosure of this material by the EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 86-5, we reserve and do not waive any rights involving this material that are or can be claimed by the company notwithstanding this submission to the EPA."

COMPANY: Monsanto Company

COMPANY AGENT: _____

J. Austin Burns, Ph.D.
Regulatory Affairs Manager

DATE: October 27, 2011

GLP COMPLIANCE STATEMENT

The materials in this volume do not meet the requirements of the Good Laboratory Practice Standards, 40 CFR Part 160. This volume provides the administrative materials for the Application to amend the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect Protected, Herbicide-Tolerant Corn with an interspersed in-field refuge configuration using a seed mixture, and therefore were not developed in compliance with 40 CFR Part 160.

10-27-2011

Submitter
J. Austin Burns, Ph.D.
Regulatory Affairs Manager

Date

10-27-11

Sponsor
Jeffrey T. Bookout, M.S., M.B.A.
Corn Regulatory Affairs Lead

Date

10/27/11

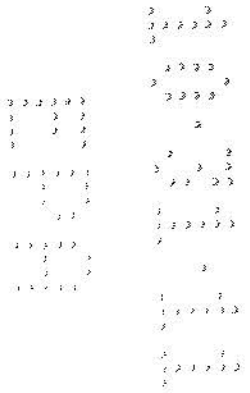
Study Director
William R. Reeves, Ph.D.
Regulatory Affairs Manager

Date

VOLUME 1

TABLE OF CONTENTS

Page



Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration ☒ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
File Symbol 524-595	Dr. Sheryl Reilly	☒ None ☐ Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	PM # 92	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167
☐ Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☒ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application.
☐ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture, to extend registration 524-595

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container	Various	☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Daniel J. Jenkins, J.D., M.S.	U.S. Agency Regulatory Affairs Manager	(202) 383-2851

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

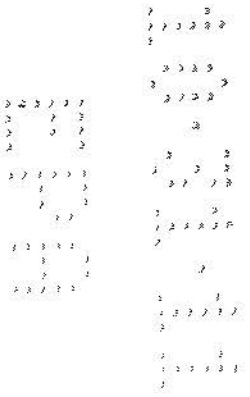
6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
	Regulatory Affairs Manager	J. Austin Burns, Ph.D. Tel. (314) 694-6514	October 27, 2011

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow Applicant Copy

CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}



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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:	EPA Registration Number / File Symbol:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 (314) 694-6514	524-595
Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7	Date: October 27, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (t) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature	Date	Typed or Printed Name and Title
J. Austin Burns	October 27, 2011	J. Austin Burns, Ph.D. Regulatory Affairs Manager

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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 524-595	Page 1 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for the Application to Amend the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture		Monsanto Company	OWN	Administrative This Submission
NA	Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010.	484234-00	Monsanto Company	OWN	Administrative Supporting Data
NA	Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010.	484234-01	Monsanto Company	OWN	Supporting Data
NA	Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	48394001	Monsanto Company	OWN	Supporting Data
NA	Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)	N/A	Monsanto Company	OWN	Supporting Data

Signature	Name and Title	Date
SIGNATURE PAGE FOR 66 PAGES	J. Austin Burns, Ph.D. Regulatory Affairs Manager	October 27, 2011

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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 524-595	Page 2 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
NA	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture	47943700	Monsanto Company	OWN	Administrative
NA	Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	47943701	Monsanto Company	OWN	Supporting Data
NA	The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn	47943702	Monsanto Company	OWN	Benefits

Signature	Name and Title	Date
See Page 1 for Signature	J. Austin Burns, Ph.D. Regulatory Affairs Manager	October 27, 2011

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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 524-581	Page 3 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Goodwin, B.K., Marra, M.C., and N.E. Piggott. 2009. Farm-Level Benefits of a Refuge Reduction for SmartStax™. A report from Agri-Analytics, Inc.	N/A	Monsanto Company	OWN	Supporting Information
	Burns, J.A. 2009. The Benefits of Refuge Reduction to 5% for SmartStax Corn	47943702	Monsanto Company	OWN	Supporting Information
	Burns, J.A. 2009. Response to U.S. EPA BPPD Letter, Dated March 19, 2009 Regarding Applications to Register MON 89034 ×TC1507 × MON 88017 × DAS-59122-7 EPA File Symbols: 524-LIR (MON); D-395123 (DAS).	N/A	Monsanto Company	OWN	Supporting Information
	Bogdanova, N., J.A. Burns, G. Head, et. al. 2009. Condition of Registration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn: Compliance Assurance Plan	47883601	Monsanto Company	OWN	Terms and Conditions
	Bogdanova, N., J. Carden, J. Lambert, et. al. 2009. Educational Materials and Information of IRM Requirements Provided by Monsanto Company to Growers of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn	47883602	Monsanto Company	DWN	Terms and Conditions

Signature	Name and Title	Date
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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 524-581	Page 4 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G., W. Moar, and N. Stozer. 2009. Insect Resistance Monitoring and a Remedial Action Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn	47883603	Monsanto Company	OWN	Terms and Conditions
	Keller, P. 2011. Annual Sales Report for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7	48367801	Monsanto Company	OWN	Terms and Conditions
	Submission of Pesticide Use Data in Support of the Registrations of MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034 (× NK603), MON 89034 × MON 88017, MON 89034 × TC1507 × MON 88017 × DAS-59122-7	48367800	Monsanto Company	OWN	Terms and Conditions
	Zahora, A. and P. Keller. 2011. 2010 Insect Resistance Management Compliance Assurance Program Report for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn	48367901	Monsanto Company	OWN	IRM
	Submission of Efficacy Data in Support of the Registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7	48369700	Monsanto Company	OWN	Product Characterization

Signature	Name and Title	Date
See Page 1 for Signature	J. Austin Burns, Ph.D. Regulatory Affairs Manager	October 27, 2011

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Date: October 27, 2011	EPA Reg. No./File Symbol: 524-581	Page 5 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G., M. Carroll, L. Stork, et. al. 2011. Corn Rootworm Adult Emergence from MON 89034 × TC1507 × MON 88017 × DAS-59122-7, MDN 88017, . DAS-59122-7, and Non-Bt Corn with Various Egg Densities in 2010 U.S. Field Trials	48369701	Monsanto Company	OWN	IRM
	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34 and Cry35 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7.		Monsanto Company	OWN	Administrative
885.1100	Burns, J.A. 2008. Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins Produced in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021223.	47444901	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F. 2008. Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021265.	47444902	Monsanto Company	OWN	Product Characterization
885.1100	Taylor, J.P., J.R Groat, and J.D. Masucci. 2007. Southern Blot Analyses to Confirm the Presence of MON 89034 and MON 88017 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0020682.	47444903	Monsanto Company	OWN	Product Characterization

Signature	Name and Title	Date
See Page 1 for Signature	J. Austin Burns, Ph.D. Regulatory Affairs Manager	October 27, 2011

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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 524-581	Page 6 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Schafer, B.W., C.Q. Cia, and S.K. Embrey. 2008. Southern Blot Analyses to Confirm the Presence of TC1507 and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Dow AgroSciences Study ID 071179.	47444904	Monsanto Company	OWN	Product Characterization
885.1100	Murphy, J.A. and J.S. McClain. 2008. Summary of Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Produced in US Field Trials in 2006. Monsanto Technical Report MSL0021266.	47444905	Monsanto Company	OWN	Product Characterization
885.1100	Stillwell, L. and A. Silvanovich. 2007. Assessment of Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021070.	47444906	Monsanto Company	OWN	Production Characterization
885.1100	Phillips, A.M. 2008. Cry34Ab1, Cry35Ab1, Cry1F, and PAT Protein Levels in Hybrid Maize TC1507, DAS-59122-7, MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and a Conventional Control from the Monsanto 2006 Production Plan 06-01-52-04. Dow AgroSciences Study ID 061026.06.	47444907	Monsanto Company	OWN	Product Characterization
N/A	Levine, S. 2008. Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021267.	47444908	Monsanto Company	OWN	Environmental Assessment

Signature	Name and Title	Date
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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 524-581	Page 7 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	MacRae, T. 2008. Evaluation of Potential for Interaction Between the *Bacillus thuringiensis* Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins. Monsanto Technical Report MSL0020554.	47444909	Monsanto Company	OWN	Environmental Assessment
N/A	Levine, S. 2008. Evaluation of the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7 by Insect Bioassay. Monsanto Technical Report MSL0021104.	47444910	Monsanto Company	OWN	Environmental Assessment
N/A	Head, G. and N. Storer. 2008. Insect Resistance Management Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021285.	47444911	Monsanto Company	OWN	IRM
N/A	Levine, S. and J. Huesing. 2008. Endangered Species Impact Assessment for the Cumbined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021268.	47444912	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M. 2008. Evaluation of Potential Dietary Effects of Pollen From the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on the Ladybird Beetle *Coleomegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL 0021036.	47444913	Monsanto Company	OWN	Environmental Assessment

Signature	Name and Title	Date
See Page 1 for Signature	J. Austin Burns, Ph.D. Regulatory Affairs Manager	October 27, 2011

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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 524-575	Page 8 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient: *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Updated Compliance Assurance Plan, Educational Materials, IRM Monitoring, and a Remedial Action Plan for MON 89034 (EPA Reg. No. 524-575) and MON 89034 × MON 88017 (EPA Reg. No. 524-576) Insect-Protected and Herbicide-Tolerant Corn	483696-01	Monsanto Company	OWN	Terms & Conditions
	Annual Sales Report for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7 (EPA Reg. Nos. 524-489, 524-528, 524-545, 524-551, 524-552, 524-575, 524-576, and 524-581)	483678-01	Monsanto Company	OWN	Terms & Conditions
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm-Protected Bt Corn, and Corn Borer / Corn Rootworm Protected Stacked Bt Corn.	483751-01	ABSTC	OWN	Terms & Conditions
	Baseline Assessment of Bt Susceptibility of Corn Earworm, *Helicoverpa zea*, to Cry1A.105; 2009 Collections and Assays (Lang, B. 2010)	48207401	Monsanto Company	OWN	IRM-Condition of Registration
	Baseline Susceptibility of the European Corn Borer, *Ostrinia nubilasis*, to Cry1A.105 and Cry2Ab2 Bt Proteins (Siegfried, B. and Spencer, T. 2010)	48207402	Monsanto Company	OWN	IRM-Condition of Registration
	2010 Insect Resistance Management Compliance Assurance Program Report for Corn Borer Protected Bt Corn MON 89034 (EPA Reg. No. 524-575)		Monsanto Company	OWN	IRM-Condition of Registration

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Baseline Susceptibility of Southwestern Corn Borer, *Diatraea grandiosella*, to Cry1A.105 and Cry2Ab2 Bt Proteins (Song, Q., Sun, Y. and Wang, Q. 2009)	48207403	Monsanto Company	OWN	IRM-Condition of Registration
	Annual Sales report for MON 810 (EPA Reg.No. 524-489], MON 863 (EPA Reg. No. 524-528), MON 863 x MON 810 (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), MON 89034 (EPA Reg. No. 524-575) and MON 89034 x MON 88107 (EPA Reg. No. 524-576)	479614-01	Monsanto Company	OWN	Terms & Conditions
	Updated Compliance Assurance Plan, Educational Materials, IRM Monitoring, and a Remedial Action Plan for MON 89034 and MON 89034× MON 88017 Insect-Protected and Herbicide-Tolerant Corn (Keller, P. 2011)	479033501	Monsanto Company	OWN	Conditions of Registration
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	471275-03	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Company	OWN	Product Characterization

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.	469514-01	Monsanto Company	OWN	Product Characterizatinn
885.1100	Rice, J.F., B.J. Wolff, J.R. Groat, N.K. Scanlon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	469514-02	Monsanto Company	OWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Monsanto Company	OWN	Product Characterization
885.1100	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and *E. coli*-Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.	469514-04	Monsanto Company	OWN	Product Characterization

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in *E.Coli* and *Bt* Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	469514-05	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masucci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068	466945-01	Monsanto Company	OWN	Product Characterization
885.1100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the Cry1A.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and *E.coli*-Produced Cry1A.105 Proteins. Monsanto Technical Report MSL-19960.	466946-04	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	471275-03	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Company	OWN	Product Characterization

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the Cry1A.105 Protein to Cry1A Class of *Bacillus thuringiensis* Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsanto Company	OWN	Product Characterization
860.1340	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsanto Company	OWN	Product Characterization
885.3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.	469514-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the *in vitro* Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	469514-07	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S. and E.A. Rice. 2005. Assessment of the *in vitro* Digestibility of the Cry1A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	469514-08	Monsanto Company	OWN	Human Health Assessment

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the Cry1A.105 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Thorp, J.J. and M.E. Goley. 2006. Assessment of the *in vitro* Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938	469514-09	Monsanto Company	OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cry1A.105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.	469514-10	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the *in vitro* Digestibility of the Cry1A.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	466946-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and Cry1A.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	466946-07	Monsanto Company	DWN	Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with Cry1A.105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Company	OWN	Human Health Assessment

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	469514-11	Monsanto Company	OWN	Human Health Assessment
885.4050	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Control or Commercial Corn. Monsanto Study 05-01-50-13. Amended Report.	469514-12	Monsanto Company	OWN	Human Health Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of *Bacillus thuringiensis* Cry1A.105 Protein. Monsanto Technical Report MSL-20230.	469514-13	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of *Bacillus thuringiensis* Cry2Ab2 Protein. Monsanto Technical Report MSL-20229.	469514-14	Monsanto Company	OWN	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	469514-15	Monsanto Company	OWN	Environmental Assessment

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (*Folsomia candida*). Monsanto Technical Report MSL-20169.	469514-16	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladocerao *Daphnia magna*: An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.	469514-17	Monsanto Company	OWN	Environmental Assessment
885.6200	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Mmsanto Technical Report MSL-20147.	469514-18	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Honeybee Larvae (*Apis mellifera* L.). Monsanto Study CA-2005-071.	469514-19	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Adult Honeybees (*Apis mellifera* L.). Monsanto Study CA-2005-072	469514-20	Monsanto Company	OWN	Environmental Assessment

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, *Coleomegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.	469514-21	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, *Coleomegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.	469514-22	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, *Orius insidiosus* (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20170.	469514-23	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, *Orius insidiosus* (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20171.	469514-24	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, *Ichneumon promissorius* (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149.	469514-25	Monsanto Company	OWN	Environmental Assessment

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.	469514-27	Monsanto Company	OWN	Environmental Assessment
885.5200	Mueth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.	469514-28	Monsanto Company	OWN	Environmental Assessment
N/A	Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the *Bacillus thuringiensis* Proteins Cry1A.105 and Cry2Ab2. Monsanto Technical Report MSL-19859.	466946-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindenmann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, *Ichneumon promissorius* (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Monsanto Company	OWN	Environmental Assessment

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Date: October 27, 2011	EPA Reg. No./File Symbol: 524-575	Page 18 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.J. and H.O. Krueger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-16177	450863-13	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified *Bacillus thuringiensis* Cry2Ab2 protein on honey bee larvae. Monsanto Technical Report MSL-16961.	453371-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (*Folsomia candida*), Amended report. Monsanto Technical Report MSL-16174.	450863-14	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (*Nasonia vitripennis*). Monsanto Technical Report MSL-16173.	450863-10	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (*Apis mellifera* L.). Monsanto Technical Report MSL-16176.	450863-08	Monsanto Company	OWN	Environmental Assessment

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Date: October 27, 2011	EPA Reg. No./File Symbol: 524-575	Page 19 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MDN 89034. Monsanto Technical Report 06-RA-39-06.	469514-30	Monsanto Company	OWN	IRM
	Bogdanova, N. and A. Crawford (2007). Public Interest Document Supporting Registrarion of *Bacillus thuringiensis* Cry1A.105 , Cry2Ab2 and Cry3Bb1 Proteins in Insect-Protected Corn MON 89034 and MON 89034 x MON 88017	472797-01	Monsanto Company	OWN	Benefits
	Bogdanova, N., S. Dubelman, M. Mueth, J. Murphy and A. Silvanovich (2007). Responses to EPA Questions Regarding Application 524-LTL to register Insect-Protected Corn MON 89034 (MRID 46951428)	471403-01	Monsanto Company	DWN	Misc.
	Bogdanova, N. , (2007) Responses to EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MDN 89034 and MON 89034 x MDN 88017 (MRID 46951400 and 46951300)	471275-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	470794-02	Monsanto Company	OWN	Misc.

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I *Insect Protection*

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Acute oral toxicity in mice: Cry1F *Bacillus thuringiensis* subsp. aizawai delta endotoxin	44691101	68467	PER	
	Effectiveness data for *Bacillus thuringiensis* var. aizawai Cry1F insect control protein as expressed in maize	44691102	68467	PER	
	Background document on resistance management	44691103	68467	PER	
	Product Characterization Data for *Bacillus thuringiensis* var. aizawai Cry1F Insect Control Protein as expressed in Maize	44714801	68467	PER	
	Characterization of Gene Inserts-*Bacillus thuringiensis* var. aizawai Cry1F Insect Control Proteins Expressed in Maize	44714802	68467	PER	
	Equivalency of Microbial and Maize Expressed Cry1F Protein; Characterization of Test Substances for Biochemical and Toxicological Studies. In Vitro Digestibility of Microbial and Maize Expressed Cry1F Protein Under Simulated Gastric Conditions	44714803	68467	PER	

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I *Insect Protection*

Ingredient: *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Quantitative ELISA Analysis of Cry1F Expression levels in Maize MPS Inbred Lines 1360, 1365, 1366, and 1369. (Interim Report)	44714804	68467	PER	
	Comparison of Amino Acid Sequence Similarity of Cry1F and PAT Proteins to Known Allergen Protein	44971701	68467	PER	
	Microbial B.t. Cry1F (truncated) Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study	45020101	68467	PER	
	Characterization of inserted genes in Cry1F maize line 1507	45020102	68467	PER	
	Effectiveness Data for *Bacillus thuringiensis* var. aizawai Cry1F Insect Control Protein as Expressed in Maize	44691102	68467	PER	
	Characterization of Expressed Cry1F Protein in Maize Tissues (Pollen, Grain, Grain-Containing Feed, and Purified Maize-Expressed Cry1F Protein) and Microbial Expressed Cry1F Delta Endotoxin by Biological and Biochemical Procedures	45020103	68467	PER	
	Quantitative ELISA Analysis of Cry1F and PAT Expression levels in and Compositional Analysis of Maize Inbred and Hybrid Lines 1362 and 1507	45020104	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Environmental Fate of Cry1F Protein incorporated into Soil	45020105	68467	PER	
	Cry1F *Bacillus thuringiensis* var. aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Articial Soil Substrate	45020106	68467	PER	
	Chronic exposure of *Folsomia candida* to bacterially expressed Cry1F protein	45020107	68467	PER	
OECD 202	*B.t.* Cry1F delta endotoxin: A 48-hour static-renewal acute toxicity test with the Cladoceran (*Daphnia magna*) using bacterially expressed *B.t.* Cry1F delta endotoxin, and pollen from maize expressing *B.t.* Cry1F delta endotoxin	45020108	68467	PER	
885.4340	Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary study with green lacewing larvae	45020109	68467	PER	
885.4340	Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary study with the ladybird beetle	45020110	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary toxicity study with parasitic hymenoptera	45020111	68467	PER	
71-2	Transgenic corn expressing *Bacillus thuringiensis* var. aizawai (*B.t.*) Cry1F delta endotoxin: A dietary toxicity study with Northern bobwhite	45020112	68467	PER	
	Field survey of beneficial arthropods associated with *Bacillus thuringiensis* Cry1F maize	45020113	68467	PER	
	Efficacy of Cry1F events TC1360 and TC1507	45020114	68467	PER	
	Cry1F binding studies	45020115	68467	PER	
	Resistance management plan for transgenic maize expressing the Cry1F insecticidal protein from *Bacillus thuringiensis* var. aizawai	45020116	68467	PER	

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Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 44714801: Supplemental data - Product characterization data for *Bacillus thuringiensis* var. aizawai: Cry1F control protein as expressed in maize	45020117	68467	PER	
	Supplement to MRID 44691101: Supplemental data - Acute oral toxicity in mice: *Bacillus thuringiensis* var. aizawai Cry1F delta endotoxin	45020118	68467	PER	
	Phosphinothricin acetyltransferase (PAT) protein: In vitro digestibility study	45041501	68467	PER	
	Non-target exposure and risk assessment for environmental dispersal of Cry1F maize pollen	45041502	68467	PER	
	Evaluation of the dietary effect(s) on honeybee development using bacterially expressed *B.t.* Cry1F delta endotoxin and pollen from maize expressing *B.t.* Cry1F delta endotoxin	45041503	68467	PER	
	Waiver request: Fish toxicity test with transgenic maize (corn) containing *Bacillus thuringiensis* var. aizaqoi (*B.t.*) Cry1F delta endotoxin	45044201	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (ptasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	High dose demonstration of Cry1F events TC1360 and TC1507: European corn borer	45131101	68467	PER	
	Toxicity of the Cry1F protein to neonate larvae of the monarch butterfly (*Danaus plexippus* (Linneaus)]	45131102	68467	PER	
	Public interest document for Cry1F-protected corn	45131103	68467	PER	
	Thermolability of Cry1F (truncated) delta endotoxin	45274801	68467	PER	
	Compositional analysis of maize MPS hybrid line 1507	45274802	68467	PER	
	Cry1F lateral flow test kit procedure for analyzing Cry1F corn grain	45279301	68467	PER	
	Method validation report for the determination of Cry1F delta endotoxin protein in grain by Enzyme-Linked Immunosorbent Assay	45279302	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 45131102: Supplemental data - High dose demonstration of Cry1F events TC1360 and TC1507: European corn borer	45307701	68467	PER	
	Waiver request: Fish toxicity test to assess the potential effects of maize containing *Bacillus thuringiensis* var. aizawai (Bt) Cry1F insecticidal protein (tCP) in native fish	45307702	68467	PER	
	Supplement to MRID 45020109: Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary toxicity study with green lacewing larvae	45307801	68467	PER	
	Supplement to MRID 45020110: Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary toxicity study with green ladybird beetle	45307802	68467	PER	
	Supplement to MRID 45020111: Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary toxicity study with parasitic hymenoptera	45307803	68467	PER	
	Supplement to MRID 45020106: Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: An acute toxicity study with the earthworm in an artificial soil substrate	45307804	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 45041503: Evaluation of the dietary effect(s) on honeybee development using bacterially expressed *B.t.* Cry1F delta endotoxin and pollen from maize expressing *B.t.* Cry1F delta endotoxin	45307805	68467	PER	
	Exposure and risk assessment of Herculex I Bt field corn pollen to Karner blue butterfly	45512901	68467	PER	
	Nutritional equivalency of *B.t.* Cry1F maize - poultry feeding study	45622001	68467	PER	
	Field survey of beneficial arthropods associated with *Bacillus thuringiensis* Cry1F maize	45648001	68467	PER	
	Field surveys of non-target invertebrate populations in *B.t.* corn	45652001	80778	PER	
	Development and characterization of Enzyme-Linked Immunosorbent Assay (ELISA) for detection of Cry1F protein	45685601	68467	PER	

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Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Independent laboratory validation of method GRM 02.13, determination of Cry1F delta endotoxin protein in corn grain by an of Enzyme-Linked Immunosorbent Assay	45685602	68467	PER	
	Supplement to MRID 45131102: Toxicity of the Cry1F protein to neonate larvae of the monarch butterfly (*Danaus plexippus* (Linneaus))	45759701	68467	PER	
	Stewardship of Herculex I Insect Protection with respect to the secondary lepidopteran pest, western bean cutworm (*Richia albicosta* Smith)	45896501	68467	PER	
	Lack of cross reactivity between Cry1F protein in Herculex I maize and the dust mite Der p7 protein with human sera positive for Der p7-IgE	46444001	68467	PER	
	Monitoring the susceptibility of European corn borer to Cry1Ab and Cry1F Bt proteins: Results from the 2004 collections and diapausing larvae collected in 2003	46583101	80778	PER	
	Stewardship of event TC1507 maize with respect to the secondary lepidopteran pests lesser corn stalk borer (*Elasmopalpus lignosellus* Zeller), southern corn stalk borer (*Diatraea crambidioides* Grote), and sugarcane borer (*Diatraea saccharalis* Fabricius)	46600201	68467	PER	

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I *Insect Protection*

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Slide presentation summarizing European corn borer and Cry1F resistance monitoring update	46695801	68467	PER	
	Insect resistance management compliance assurance program report for corn borer-protected Bt corn	46747801	80778	PER	
	Field surveys of non-target invertebrate populations in Bt corn: Supplement to MRID No. 45652001	46784601	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2005 monitoring results	46874901	80778	PER	
	Research results on 2004 European corn borer collections from Hamilton County, Iowa: Cry1F	47011201	68467	PER	
	Insect resistance management compliance assurance program report for corn borer-protected Bt corn, corn rootworm-protected Bt corn, and corn borer/corn rootworm protected stacked Bt corn	47044401	80778	PER	

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Regulatory Affairs Manager

Date: October 27, 2011

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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 68467-2	Page 30 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2006 monitoring results	47118401	80778	PER	
	Soil accumulation of Cry1F after three years of cropping with Herculex I corn	47120701	68467	PER	
	TC1507 maize and fall armyworm in Puerto Rico	47176001	68467	PER	
	Proposed revisions to tRM-related registration requirements for Cry1 plant-incorporated protectants in field corn	47407001	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2007 monitoring results	47413901	80778	PER	
	Proposed revisions to tRM-related registration requirements for Cry1 plant-incorporated protectants in field corn	47543901	80778	PER	

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Date: October 27, 2011	EPA Reg. No./File Symbol: 68467-2	Page 31 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2008 monitoring results	47841801	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2009 monitoring results	47971001	80778	PER	
	Production Report and Certificate of Analysis of Truncated Cry1F (TSN104550)	48193001	68467	PER	
	2010 Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375001	80778	PER	
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375101	80778	PER	

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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 524-551	Page 32 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017	

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Conditions of Registration for MON 88017 (EPA Reg. Nn.524-551) and MON 89034 x MON 88017 (EPA Reg. No.524-576), and Response to EPA's Request for Additional Information on Monsanto's Resistance Corn Rootworm (CRW) Monitoring Program.	484368-01	Monsanto Company	OWN	Terms & Conditions
	Conditions of Registration for MON 88017 (EPA Reg. No. 524-551) and Conditions of Registration for MON 89034 x MON 88017 (EPA Reg. No. 524-576).	484368-01	Monsanto Company	OWN	Terms & Conditions
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm-Protected Bt Corn, and Corn Borer / Corn Rootworm Protected Stacked Bt Corn.	483751-01	ABSTC	PER	Terms & Conditions
	Annual Sales Report for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7 (EPA Reg. Nos. 524-489, 524-528, 524-545, 524-551, 524-552, 524-575, 524-576, and 524-581).	483678-01	Monsanto Company	OWN	Terms & Conditions
	2009 Season Monitoring for the susceptibility of Neonate Western Corn Rootworm Larvae to the *Bacillus thuringiensis* Cry3Bb1 Protein.	N/A	Monsanto Company	OWN	Terms & Conditions
	2009 Season Monitoring for the Susceptibility of Neonate Western Corn Rootworm Larvae to the *Bacillus thuringiensis* Cry3Bb1 Protein.	482080-01	Monsanto Company	OWN	Terms & Conditions

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017	

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submiter	Status	Note
	2009 Insect Resistance Management Compliance Assurance Program Report for Corn Borer-Protected Bt Corn (EPA Reg. Nos. 524-489, 68467-2, 67979-1, and 29964-3), Corn Rootworm-Protected Bt Corn (EPA Reg. Nos. 524-528, 524-551, 68467-5, 67979-5, and 29964-4), and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn (EPA Reg. Nos. 524-545, 524-552, 524-576, 68467-6, 67979-8, and 29964-5).	479710-01	ABSTC	PER	Terms & Conditions
	Annual Sales report for MON 810 (EPA Reg.No. 524-489), MON 863 (EPA Reg. No. 524-528), MON 863 x MON 810 (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), MON 89034 (EPA Reg. No. 524-575) and MON 89034 x MON 88107 (EPA Reg. No. 524-576).	479614-01	Monsanto Company	OWN	Terms & Conditions
	2008 Season Monitoring for the Susceptibility of Neonate Western Corn Rootworm Larvae to the *Bacillus thuringiensis* Cry3Bb1 Protein.	478846-01	Monsanto Company	OWN	Terms & Conditions
	2008 Insect Resistance Management Compliance Assurance Program Report for Corn Borer-Protected Bt Corn (EPA Reg. Nos. 524-489, 68467-2, 67979-1, and 29964-3), Corn Rootworm-Protected Bt Corn (EPA Reg. Nos. 524-528, 524-551, 68467-5, 67979-5, and 29964-4), and Corn Borer/Corn rootworm-Protected Stacked Bt Corn (EPA Reg. Nos. 524-545, 524-552, 68467-6, 67979-8, and 29964-5).	476633-01	ABSTC	PER	Terms & Conditions

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017	

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Annual Sales Report for YieldGard Corn Borer Corn (EPA Reg. No. 524-489), YieldGard Rootworm Corn (EPA Reg. No. 524-528), YieldGard Plus Corn (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), and MON 88017 × MON 810 (EPA Reg. No. 524-552).	476631-01	Monsanto Company	OWN	Terms & Conditions
	2006 Insect Resistance Management Compliance Assurance Program for Corn Borer-Protected Bt Corn, Corn Rootworm-Protected Bt Corn and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn. (ABSTC Report).	470444-01	ABSTC	PER	Terms & Conditions
	Submission of Annual Sales Report for YieldGard® Corn Borer corn (EPA Reg. No. 524-489), YieldGard® Rootworm corn (EPA Reg. No. 524-528), YieldGard® Plus corn (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551) and MON 88017 x MON 810 (EPA Reg. No. 524-552), (2007).	470431-01	Monsanto Company	OWN	Terms & Conditions
	Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 toxin from *Bacillus thuringiensis*: 2005 Data Summary.	469491-01	Monsanto Company	OWN	Terms & Conditions

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry3Bb1 Protein Produced in MON 88017. MSL-18835	461817-01	Monsanto Company	OWN	Product Characterization
885.1100	Beasley, K. A., H.M. Anderson., P.B. Wimberley, D.W. Mittank., and R.P. Lirette (2002). Molecular analysis of YieldGard®Rootworm/Roundup Ready®Corn Event MON 88017. MSL-17609	461817-02	Monsanto Company	OWN	Product Characterization
885.1100	Bhakta, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002. MSL-18823	461817-03	Monsanto Company	OWN	Product Characterization
885.1100	Duan, J. J., M. S. Paradise and C. Jiang (2003). Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran species. MSL-18799	461817-04	Monsanto Company	OWN	Product Characterization
885.1100	Hileman, R. E. and J. D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in MON 863. MSL-17137	454240-10	Monsanto Company	OWN	Product Characterization

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E., G. Holleschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by *E. coli* Fermentation and MON 863. MSL-17274	455382-01	Monsanto Company	OWN	Product Characterization
860.1340	Brown, M. (2003). *TraitChek*™ Cry3Bb Lateral Flow Test Strip and *SeedChek*™ Cry3Bb ELISA Performance Verification for Corn Seed, Leaf, and Composite Testing. MSL-19581, in unpublished study conducted by Strategies Diagnostics, Inc.	463942-01	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y. A., B-P. Tonnu, L. D. Albee and R. P. Lirette (2001). Amended Report for MSL-16559: *B.t.* Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. MSL-17181	454240-01	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran Species" (MRID No. 461817-04)	465783-03	Monsanto Company	OWN	Product Characterization
885.1100	Thoma, R. S., G. Holleschak, R. E. Hileman and J. D. Astwood (2001). Primary Structural Protein Characterization of MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154	454240-11	Monsanto Company	OWN	Product Characterization

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Submission of Supplemental Data (May 21, 2001) in Support of the Application for Registration of MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI.	N/A	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y., B-P. Tonnu and R. P. Lirette (2001). Cry3Bb1, Cry1Ab and NPTII Protein Levels in the Dual-trait Maize Hybrid MON 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. MSL-17266	457917-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of *B.t.* Protein 11098, *B.t.* Protein 11231 and NPTII Protein Expressed in Corn Events MON 853 and MON 860 to Microbial Sources. MSL-17222	454240-04	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002" (MRID No. 461817-03)	465783-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.11098 and NPTII Proteins in Corn Event MON 863 to Microbial Sources. MSL-17220	454240-05	Monsanto Company	OWN	Product Characterization

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Supplemental Information for "Molecular Analysis of YieldGard® Rootworm/Roundup Ready® Corn Event MON 88017" (MRID No. 461817-02)	465783-01	Monsanto Company	OWN	Product Characterization
860.1340	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. Monsanto Ref. No. 99-640E-1.	453731-01	Monsanto Company	OWN	Product Characterization
N/A	Astwood, J. D., R. E. Hileman, M. J. McKee, T. J. Rydel, J. W. Seale and L. English (2001). Safety Assessment of Cry3Bbt Variants in Corn Rootworm Protected Corn. MSL-17225	454240-09	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the *in vitro* Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530	455770-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bbt.11098 and Cry3Bb1.t1231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment. MSL-17223	454240-07	Monsanto Company	OWN	Human Health Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3050	Bechtel, C. L. (1999). Acute Oral Toxicity of *B.t.* Protein 11231 in Mice. MSL-16216.	449043-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140	454240-08	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Mice with *E. coli* Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382	455382-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman and J. D. Astwood (2001) Assessment of the *in vitro* Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from *E. coli*. MSL-17292	455382-03	Monsanto Company	OWN	Human Health Assessment
885.3050	Bechtel, C. L. (1999). Acute Oral toxicity of *B.t.* Protein 11098 in Mice. MSL-16215	449043-06	Monsanto Company	OWN	Human Health Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of *B.t.* Protein 11098 and *B.t.* Protein 11231 Sequences Utilizing Toxin and Public Domain Genetic Databases. MSL-15870	449043-08	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of *B.t.* Protein 11098 and *B.t.* Protein 11231 Sequences Utilizing an Allergen Database. MSL-15873	449043-09	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the *In Vitro* Digestibility of *B.t.* protein 11098 and *B.t.* 11231 Utilizing Mammalian Digestive Fate Models. MSL-17166	454240-06	Monsanto Company	OWN	Human Health Assessment
885.4200	McKee, M. J. (2001). Bluegill Dietary Toxicity Study for the *Bacillus thuringiensis* Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383	455382-00	Monsanto Company	OWN	Environmental Assessment
885.4240 Series 72, Subdivision E	Drottar, K. R. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (*Daphnia magna*). MSL-16163	449043-18	Monsanto Company	OWN	Environmental Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4280	Results of acute toxicity tests with *Daphnia* and catfish did not produce any evidence of adverse effects. Estuarine and Marine animal studies are waived for this product because of the very low to no potential for exposure to Cry3Bb1 protein from field corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Texiera, D. (2005). Evaluation of Dietary Effects of a Cry3Bb1 Protein Variant on Minute Pirate Bugs (*Orius insidiosus*). MSL-19697	464799-05	Monsanto Company	OWN	Environmental Assessment
885.4300	Since the active ingredient in this product is an insect toxin (Bt endotoxin) that has never shown any toxicity to aquatic or terrestrial plants, these studies have been waived for this product. The Agency has determined there is no significant risk of gene capture and expression of Cry3Bb1 protein by wild or weedy relatives of corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Palmer, S. J. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (*Hippodamia convergens*). MSL-16166	449043-14	Monsanto Company	OWN	Environmental Assessment
850.6200	Hoxter, K. A., S. J. Palmer and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162	449043-16	Monsanto Company	OWN	Environmental Assessment

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Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the *Bacillus thuringiensis* Protein 11098 to Collembola (*Folsomia candida*). MSL-15988	449043-17	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11231: A Dietary Study with Green Lacewing Larvae (*Chrysoperla carnea*). MSL-16165	449043-12	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11231: A Dietary Study with the Parasitic Hymenoptera (*Nasonia vitripennis*). MSL-16167	449043-13	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., M. Bhatti, B. Ayden, J. Murphy, S. Levine and C. Jiang (2005). Environmental Fate of Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-19285	465103-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic *Bacillus thuringiensis* (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, *Coleomegilla maculata*. MSL-16936	453613-01	Monsanto Company	OWN	Environmental Assessment

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Bryan, R. L., J. R. Porch and H. O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, *Hippodamia convergens*. MSL-17171	453613-02	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179	455382-06	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., M. J. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic *Bacillus thuringiensis* (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, *Coleomegilla maculata*. MSL-16907	455382-04	Monsanto Company	OWN	Environmental Assessment
885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (*Danus plexippus*) via Laboratory Bioassay. MSL-17235	455382-05	Monsanto Company	OWN	Environmental Assessment
N/A	Head, G., M. Picau, S. Sivasupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein *in vitro*. C3NTO	455382-07	Monsanto Company	OWN	Environmental Assessment

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MDN 863. MSL-17614	455770-03	Monsanto Company	OWN	Environmental Assessment
154-2300	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. Monsanto Reference No. 00-CR-032E-7	456530-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., J. D. Duan, C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MDN 863 Event: 2000 - 2001 Field Trials. Report MSL-17531	457916-01	Monsanto Company	OWN	Environmental Assessment
850.6200	Sindermann, A. B., J. R. Porch and H. D. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137	457571-01	Monsanto Company	OWN	Environmental Assessment
885.4050	Gallagher, S. P., J. Grimes and J. B. Beavers (1999). *Bacillus thuringiensis* Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161	449043-15	Monsanto Company	OWN	Environmental Assessment

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V. L. (1999). Evaluation of the Dietary Effect(s) of Purified *Bacillus thuringiensis* Protein 11231 on Adult Honey Bees (*Apis mellifera* L.). MSL-16169	449043-11	Monsanto Company	OWN	Environmental Assessment
885.5200	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudin (2000). Aerobic Soil Degradation of the *B.t.* Protein 11098 as a Component of Insect Protected Corn. MSL-16440	451568-04	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the *Bacillus thuringiensis* Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected MON 863. MSL-17102	457571-02	Monsanto Company	OWN	Environmental Assessment
885.4050	George, B. (2001). Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. MSL-17243	459415-01	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified *Bacillus thuringiensis* Protein 11231 on Honey Bee Larvae. MSL-16168	449043-10	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, J. Colyer, B. Ledesma, S. Levine, F. Lloyd, G. Mueller, J. Warren & C. Jiang (2007) Environmental Fate of the Cry3Bb1 and Cry1Ab Proteins in Corn Fields Planted with MON 863 x MON 810 for Three Consecutive Years MSL-20589	472829-02	Monsanto Company	OWN	Environmental Assessment

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-3500	Duan, J., M. Bhatti, C. Brown, G. Head, C. Jiang, C. Pilcher, C. Pilcher, D. Carson & T. Nickson (2007) Two Year Field Assessment of the Effect of Combined Trait Bt Corn Mon 863 x MON 810. MSL-19696	472829-01	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, M.J. McKee, M.A. Nemeth, D. Ward, G. Head, S. Levine, M. Bhatti and M. Paradise (2004). Statistical Power Analysis of a Two-Year Field Study Evaluating the Ecological Effect of Corn Event MON 863. MSL-19246	462627-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, C. Brown, M. Bhatti, M. Nemeth, T. Nickson and D. Ward (2004). Supplemental Statistical Analysis of Data from a Two-Year Field Census Study with Corn Event MON 863. MSL-19329	463942-02	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman S., M. Bhatti and B. Ayden (2004). Interim Repon: Assessment of the Environmental Fate of the Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-18931	462001-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan J. and M. Paradise (2005). Evaluation of Dietary Effects of Cry3Bb1 Protein on the Ground Beetle *Poecilus chalcites* (Coleoptera:Carabidae). MSL-19631	464799-04	Monsanto Company	OWN	Environmental Assessment
154-3500	Head, G. (2004). Research on the Effects of Corn Rootworm Protected Transgenic Corn on Non-Target Organisms: Publications & Manuscripts.	462627-02	Monsanto Company	OWN	Environmental Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4150	Mammalian wildlife exposure to Cry3Bb1 protein is considered likely; however, the Cry3Bb1 toxicity data for Human Health Assessment indicate that there is no significant toxicity to rodents form testing at the maximum hazard dose. Therefore no hazard to mammalian wildlife is anticipated.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4200	Li, M. H. and E. H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164	449043-19	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003). Data Waiver Request: Toxicity of *B.t.* Cry3Bb1 Protein in the Red Milkweed Beetle (*Tetraopes* sp.). MSI-18741	N/A	Monsanto Company	OWN	Environmental Assessment Granted in BRAD
N/A	Pilcher, C. D. (2001). Efficacy of MDN 863 Against Corn Rootworm and Comparison to Insecticide Treatments – Results of Year 2000 Field Trials. Monsanto Ref. No. 00-CR-032E-3	453613-03	Monsanto Company	OWN	Benefits
N/A	Mitchell, P. D. (2002). Yield Benefit of MON 863. MSL-17782	456530-02	Monsanto Company	OWN	Benefits

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in MON 863. MSL-17766	456530-01	Monsanto Company	OWN	Benefits
N/A	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR12L, ZMIR13L and ZMIR14L). Monsanto Ref. No. 99-781E	450297-01	Monsanto Company	OWN	Benefits
N/A	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - YieldGard® Rootworm. MSL-17993	456923-01	Monsanto Company	OWN	Benefits
N/A	Vaughn, T. T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (*Diabrotica barberi*), Southern Corn Rootworm (*D. undecimpunctata howardi*), and Western Corn Rootworm (*D. virgifera virgifera*). MTC RPT4	455382-08	Monsanto Company	OWN	Benefits
N/A	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556	455770-01	Monsanto Company	OWN	Benefits/IRM

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Vaughn, T. (2004). Progress Repon on Insect Resistance Management for Corn Event MON 863.	461865-01	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	IRM
N/A	Head, G. and K. Reding. (2006). Corn rootworm Insect Resistance Management Research (fourteen journal publications)	467424-01	Monsanto Company	OWN	IRM
N/A	Davis, P., G. Head, J. McFerson et. al. (2000). Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	451568-05	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4	459438-01	Monsanto Company	OWN	IRM

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	T. Vaughn (2005). Second Progress Report on Insect Resistance Management for Corn Event MON 863. REVISED	N/A	Monsanto Company	OWN	IRM
N/A	Letter submitted May 23, 2003 to EPA with 12 research protocols on the biology and ecology of the corn rootworm pest complex.	N/A	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2004). 2004 Progress Report for the Corn Event MON 863 Resistance Monitoring Program.	462627-01	Monsanto Company	OWN	IRM
N/A	Administrative Materials in Support of the Registration of *Bacillus thuringiensis* Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	451568-00	Monsanto Company	OWN	Tolerance Exemption
N/A	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant *Bacillus thuringiensis* Corn Rootworm Control Protein, as Produced in the Corn (*Zea mays*, L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	449043-00	Monsanto Company	OWN	Tolerance Exemption

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See **Page 1 for Signature**	J. Austin Burns, Ph.D. Regulatory Affairs Manager	October 27, 2011

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017	

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Petition for Exemption from the Requirement of a Tolerance for *Bacillus thuringiensis* Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients.	PP 7F4888	Monsanto Company	OWN	Tolerance Exemption
885.1100	McCoy, R. L. and A. Sivanovich (2003). Bioinformatics Analysis of the CP4 EPSPS Protein Utilizing the AD4, TOXINS and ALLPEPTIDES Databases. MSL18752	466361-01	Monsantn Company	OWN	Inert Ingredient
885.1100	McCoy, R.L. and A. Sivanovich (2005). Updated Bioinformatics Evaluation of the CP4 EPSPS Protein Utilizing the AD5 Database. MSL19894	466361-02	Monsanto Company	DWN	Inert Ingredient
885.3050	Monsanto Company (1995). Submission of Toxicology Data in Support of a Tolerance Petition for CP4 EPSPS as a Plant Pesticide Formulation Inert Ingredient. Transmittal of 1 Study.	436919-00	Monsanto Company	OWN	Inert Ingredient
885.3050	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgette (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12: 92-419-7t9	436919-01	Monsanto Company	OWN	Inert Ingredient

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017	

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Padgette, S., G. Barry, D. Re, D. Eichholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-enolpyruvylshikimate-3-phosphate Synthase from *Agrobacterium sp.* Strain CP4. MSL-12738	438076-01	Monsanto Company	OWN	Inert Ingredient
885.1100	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant *Escherichia coli* Fermentation. MSL-12389	438076-02	Monsanto Company	OWN	Inert Ingredient
885.1100	Heeren, R., S. Padgette and M. Gustafson (1993). The Purification of Recombinant *Escherichia coli* CP4 5-enolypyruvylshikimate-3-phosphate synthase for Equivalence Studies. MSL-12574	438076-03	Monsanto Company	OWN	Inert Ingredient
N/A	Monsanto Company (1995). Submission of Product Chemistry, Toxicology and Pesticide Fate in Animals Data in Support of the Exemption for the Requirement of a Petition for Tolerance for CP4 EPSPS. Transmittal of 4 studies.	436433-00	Monsanto Company	OWN	Inert Ingredient
885.1100	Harrison, L., M. Bailey, R. Leimgruber, C. Smith, D. Nida, M. Taylor, M. Gustafson, B. Heeren and S. Padgette (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPS. Lab Project Number: 92/01/30/14: 12901	436433-01	Monsanto Company	OWN	Inert Ingredient

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Lee, T., M. Bailey, C. Smith, J. Zeng, E. Elswick and P. Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in *Escherichia coli* and European Corn Borer Resistant Corn. Lab Project Number: 94-01-39-10: MSL-13920	436433-02	Monsanto Company	OWN	Inert Ingredient
885.3050	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92223	436433-03	Monsanto Company	OWN	Inert Ingredient
885.1100	Ream, J., M. Bailey, J. Leach and S. Padgette (1993). Assessment of the in vitro Digestive Fate of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949	436433-04	Monsanto Company	OWN	Inert Ingredient
N/A	Revisions and Clarification to the Terms & Conditions of Registration for Corn Event MON 863 and YieldGard® Plus Corn; Progress Report on Multiple IRM-Related Activities for MON 863; and Response to EPA Letter Dated August 13, 2004. Submitted 7/7/2005.	N/A	Monsanto Company	OWN	Terms & Conditions
N/A	Siegfried, B. and T. Spencer (2005). Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 Toxin from *Bacillus thuringiensis*. This report satisfies the Insect Monitoring Terms & Conditions.	467259-01	Monsanto Company	OWN	Terms & Conditions

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW *Insect Protection*	

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product characterization data for *Bacillus thuringiensis* PS149B1 13.6 kDa and 43.8 kDa insecticidal crystal proteins expressed in transgenic maize plants	45242201	68467	PER	
	Equivalency of microbial and maize-expressed PS149B1 proteins	45242203	68467	PER	
	Microbial PS149B1 Binary Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study	45242204	68467	PER	
	Comparison of the Amino Acid Sequence of the *Bacillus thuringiensis* Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Allergens	45242205	68467	PER	
	Characterization of *Pseudomonas* produced and transgenic maize expressed phosphinothricin acetyltransferase (PAT) protein	45242206	68467	PER	
	PS149B1 14 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242207	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW *Insect Protection*	

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242208	68467	PER	
	PS149B1 14 KDA and 44 KDA Proteins: Acute Oral Toxicity study in CD-1 Mice	45242209	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: A Dietary Toxicity Study with the Ladybird Beetle	45242210	68467	PER	
	The Tri-Trophic Interaction Between PS149B1 Transformed Maize, Corn Leaf Aphid and Ladybird Beetle	45242211	68467	PER	
	In Vitro Digestibility of PS149B1 Proteins	45242212	68467	PER	
	Quantitative ELISA analysis of PS149B1 protein expression levels in hybrid and inbred lines of maize event TC5639 (interim report)	45242213	68467	PER	

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW *Insect Protection*

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Degradation of Microbial Binary PS149B1 Delta-Endotoxin in a Representative Soil from the Mid-Western USA Maize-Growing Region	45242214	68467	PER	
	Product durability plan for transgenic maize expressing insecticidal crystal protein from *Bacillus thuringiensis* strain PS149B1 during the experimental use period	45242215	68467	PER	
	Field efficacy of PS149B1 maize events against corn rootworms	45242216	68467	PER	
	Microbial PS149B1 Binary Insecticidal Crystal Protein, Pollen Expressing PS149B1 Binary Insecticidal Crystal Protein, and Individual PS149B1 14kDa and 44 kDa Insecticidal Crystal Proteins	45340701	68467	PER	
	Thermolability of PS149B1 Binary Delta-Endotoxin	45358401	68467	PER	
	PS149B1binary insecticidal crystal protein: Acute toxicity study to the earthworm in an artificial substrate	45360201	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW *Insect Protection*	

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Lateral flow test kit method validation for the detection of the PS149B1 14 kDa and 44 kDa protein in maize grain	45383401	68467	PER	
	Heat lability of individual proteins of the PS149B1 binary ICP	45584501	68467	PER	
	In Vitro Simulated Gastric Fluid Digestibility Study of Microbially Derived Cry34Ab1 Protein	45584502	68467	PER	
	Characterization of Cry34Ab1 and Cry35Ab1 from Recombinant *Pseudomonas fluorescens* and Transgenic Maize	45790401	68467	PER	
	Characterization of DNA Inserted into Transgenic Corn Events (Cry34Ab1 and Cry35Ab1)	45790402	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, *Oncorhynchus mykiss*, Walbaum	45790403	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Daphnid, *Daphnia* magna Straus	45790404	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW *Insect Protection*	

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera (*Nasonia vitripennis*)	45790405	68467	PER	
	Assessment of Chronic Toxicity of Diet Containing *Bacillus thuringiensis* PS149B1 Insecticidal Crystal Protein to Collembola (*Folsomia candida*)	45790406	68467	PER	
	PS149B1 Insecticidal Crystal Protein: Dietary Toxicity to Green Lacewing Larvae (*Chrysoperla carnea*)	45790407	68467	PER	
	SDS-PAGE Sensitivity Analysis for Cry35Ab1 in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212	45790408	68467	PER	
	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Ab1 and Cry35Ab1	45790509	68467	PER	
	Field Efficacy of Cry34Ab1/Cry35Ab1 Maize Events Against Corn Rootworms	45790410	68467	PER	
	Product characterization data for *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins expressed in transgenic maize plants (PHP17658)	45790501	68467	PER	
	Product Characterization Data for *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 Proteins Expressed in Transgenic Maize Plants (PHP17662)	45790601	68467	PER	

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW *Insect Protection*

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Summary of Heat Lability Studies with Cry34Ab1/Cry35Ab1	45808601	68467	PER	
	Quantitative ELISA analysis of Cry34Ab1 and Cry35Ab1 proteins expressed in maize plants transformed with the vector PHP17658	45833101	68467	PER	
	Quantitative ELISA analysis of Cry34Ab1 and Cry35Ab1 proteins expressed in maize plants transformed with the vector PHP17662	45833102	68467	PER	
	Quantitative ELISA Analysis of Cry34Ab1 and Cry35Ab1 Proteins Expressed in Maize Plants Transformed with the Vector PHP17662	45833201	68467	PER	
	Slide Presentation Summarizing Cry34Ab1/Cry35Ab1 Heat Inactivation Studies.	45860201	68467	PER	
	Probe MOA studies to assess potential for protein synthesis inhibition by *Bacillus thuringiensis* PS149B1 Cry34Ab1/Cry35Ab1 proteins in rabbit reticulocyte assay; Re-examination of lab notebook data	45942801	68467	PER	
	Product characterization data for *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins expressed in transgenic maize plants (PHP17662)	46030001	68467	PER	
	Independent Laboratory Validation Pioneer Hi-Bred International, Inc. ELISA Method for the Quantification of Cry34Ab1Protein from Transgenic Plants	46123901	68467	PER	
	Independent Laboratory Validation of Dow AgroSciences Method GRM 03.13, "Determination of Cry35Ab1 Insecticidal Crystal Protein in Maize Tissue by Enzyme-Linked Immunosorbent Assay"	46123902	68467	PER	

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Product: Herculex® RW *Insect Protection*

Ingredient: *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cry34/35 Protein Distribution and Familiarity	46123903	68467	PER	
	Agronomic Characteristics, Quantitative ELISA and Nutrient Composition Analysis of Hybrid Maize Lines Containing Cry34Ab1, Cry35Ab1 and PAT Genes: Chile Locations	46123904	68467	PER	
	Biological equivalency of Cry34/35Ab1 insecticidal crystal protein in transgenic plants and derived from transgenic *Pseudomonas fluorescens*	46123905	68467	PER	
	Characterization of Cry34Ab1 and Cry35Ab1 Proteins Derived from Transgenic Maize event E4497.59.1.22 (DAS-59122-7)	46123906	68467	PER	
	Characterization of Phosophinothricin Acetyltransferase (PAT) Derived from Transgenic Maize Event E4497.59.1.22	46123907	68467	PER	
	Characterization of DNA Inserted into Transgenic Corn Events DAS-45216-6 and DAS-59122-7	46123908	68467	PER	

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Product: Herculex® RW *Insect Protection*

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Detailed characterization of DNA inserted into transgenic corn events DAS-45216-6 and DAS-59122-7	46123909	68467	PER	
	Evaluation of microbe derived Cry34Ab1 and Cry35Ab1 proteins for protein synthesis inhibition activity	46123910	68467	PER	
	Nutritional Equivalency Study of Maize Containing Cry34Ab1 and Cry35AB1: Poultry Feeding Study	46123911	68467	PER	
	The effect of Cry34Ab1/Cry35Ab1 proteins on the development and mortality of the Ladybird beetle *Coleomegilla maculata* DeGeer	46123912	68467	PER	
	Non-target Invertebrate Ecological Risk Assessment for Field Corn Expressing Cry34Ab1 and Cry35Ab1 Insecticidal Crystal Proteins in Event DAS-591227	46123913	68467	PER	
	Evaluation of the impact of corn rootworm control strategies on non-target arthropods	46123914	68467	PER	

Signature	Name and Title	Date
See Page 1 for Signature	J. Austin Burns, Ph.D. Regulatory Affairs Manager	October 27, 2011

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Form Approved OMB No. 2070-0060

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

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DATA MATRIX

Date: October 27, 2011	EPA Reg. No./File Symbol: 68467-5	Page 62 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW *Insect Protection*	

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Investigations into Dose of Cry34Ab1/Cry35Ab1 Rootworm-Resistant Maize Event DAS-59122-7 Against Western and northern Corn Rootworms in Support of Trait Durability Plans	46123915	68467	PER	
	Effect on Western Corn Rootworm Adults of Feeding on Cry34/35Ab1-Corn Rootworm Protected Corn Tissue and Implications for Product Durability	46123916	68467	PER	
	Evaluation of endangered/threatened insect species relative to the use of Cry34Ab/Cry35Ab1 corn rootworm-resistant maize hybrids	46123917	68467	PER	
	Trait Durability Plan for Cry34/35 Corn Rootworm Protected corn Event DAS-59122-7 Following Commercialization	46123918	68467	PER	
	Simulations of Corn Rootworm Adaptation to Cry34/35 Corn Rootworm Protected Corn in Support of Trait Durability Plans for Event DAS-59122-7	46123919	68467	PER	
	Digestion of Allergenic and Non-Allergenic Proteins in Simulated Gastric Fluid	46123920	68467	PER	

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Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Public Interest Document for Cry34/35Ab1 Corn Rootworm-Protected Corn	46123921	68467	PER	
	Investigation of Potential Interaction between Cry1F and the Binary Cry34Ab1/Cry35Ab1 Proteins	46343806	68467	PER	
	Digestion efficiency of allergens and non-allergens in simulated gastric fluid: *Bacillus thuringiensis* Cry 34/35Ab1 construct PHP17662	46388601	68467	PER	
	Lack of Cry34Ab1/Cry35Ab1 co-association in solution	46556801	68467	PER	
	Evaluation of the Sequence Similarities of the Cry34Ab1, cry35Ab1, and PAT Proteins to the Public Protein Sequence Datasets	46584701	68467	PER	
	Summary report of a carabid beetle laboratory toxicity study using Cry34Ab1 and Cry35Ab1 including copies of references	46714101	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW *Insect Protection*	
Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Preliminary resistance monitoring plan for Cry34/35Ab1 corn event DAS-59122-7	46769201	68467	PER	
	Detailed resistance monitoring plan for Cry34/35Ab1 corn event DAS-59122-7	47334201	68467	PER	
	Evaluation of potential dietary effects of Cry34/35Ab1 protein on insidious flower bugs, *Orius insidiosus* (Hemiptera: Anthocoridae)	47436701	68467	PER	
	Monitoring corn rootworm susceptibility to Cry34/35Ab1 event DAS-59122-7: 2007 insect collections	47522501	68467	PER	
	Three-Year Field Monitoring of Cry34/35Ab1 and Cry1F x Cry34/35Ab1 Maize Hybrids for Nontarget Arthropod Effects	47870301	68467	PER	
	Monitoring corn rootworm susceptibility to Cry34/35Ab1 event DAS-59122-7: 2008 insect collections	47900801	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW *Insect Protection*	

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Soil accumulation of Cry34Ab1 and Cry35Ab1 proteins after three years of cropping with DAS-59122-7 corn	47959501	68467	PER	
	Investigating Performance of Herculex™ RW and Herculex™ XTRA Under Commercial Use	48045501	68467	PER	
	Monitoring Corn Rootworm Susceptibility to Cry34/35Ab1 Event DAS-59122-7: 2009 Growing Season	48279701	68467	PER	
	2010 Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375001	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375101	68467	PER	
	Revised Guidelines for Evaluating Unexpected Corn Rootworm Damage in Herculex® RW and Herculex® XTRA	48430701	68467	PER	

Signature	Name and Title	Date
See Page 1 for Signature	J. Austin Burns, Ph.D. Regulatory Affairs Manager	October 27, 2011

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SUMMARY OF THE APPLICATION

The subject of this application is for the registration extension of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect Protected, Herbicide-Tolerant Corn (Genuity® SmartStax® RIB Complete™; EPA Reg. No. 524-595).

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ was conditionally registered on April 8, 2011. The initial time-limited registration expired on October 31, 2011, which was subsequently extended to November 30, 2011. This current application request is to extend EPA Reg. No. 524-595 for a period of two years beyond the current November, 30, 2011 expiration date based on the EPA's registration decision in the BRAD for this product (EPA Docket ID EPA-HQ-OPP-2011-0362-0002, April 8, 2011; p27). An updated data matrix is being supplied with this application. With the exception of the revised label to incorporate bag-tag language suitable for both the corn- and cotton-growing areas as required under the current terms and conditions, no other changes are being requested to the registration conditions as part of this registration extension request.

® Genuity and SmartStax are registered trademarks of Monsanto Technology LLC.
™ RIB Complete is a trademark of Monsanto Technology, LLC.

PRODUCT LABEL

The subject of this application is for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™. No substantive changes to the label for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-Protected, Herbicide-Tolerant Corn in EPA Reg. No. 524-595, as updated April 8, 2011, are being requested. The patent numbers have been updated. Five copies of the proposed label for the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ are attached.

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7
RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1)... ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ..... ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ should be sown on the same day, or with the shortest window possible between

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)	*Ostrinia nubilalis*
Southwestern corn borer (SWCB)	*Diatraea grandiosella*
Southern cornstalk borer (SCSB)	*Diatraea crambidoides*
Corn earworm (CEW)	*Helicoverpa zea*
Fall armyworm (FAW)	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Lesser corn stalk borer	*Elasmopalpus lignosellus*
Sugarcane borer (SCB)	*Diatraea saccharalis*
Western bean cutworm (WBC)	*Richia albicosta*
Black cutworm	*Agrotis ipsilon*
Western corn rootworm (WCRW)	*Diabrotica virgifera virgifera*
Northern corn rootworm (NCRW)	*Diabrotica barberi*
Mexican corn rootworm (MCRW)	*Diabrotica virgifera zeae*

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: __/__/__

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn

(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡

(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1)... ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ..... ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

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Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

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The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ should be sown on the same day, or with the shortest window possible between

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)	*Ostrinia nubilalis*
Southwestern corn borer (SWCB)	*Diatraea grandiosella*
Southern cornstalk borer (SCSB)	*Diatraea crambidoides*
Corn earworm (CEW)	*Helicoverpa zea*
Fall armyworm (FAW)	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Lesser corn stalk borer	*Elasmopalpus lignosellus*
Sugarcane borer (SCB)	*Diatraea saccharalis*
Western bean cutworm (WBC)	*Richia albicosta*
Black cutworm	*Agrotis ipsilon*
Western corn rootworm (WCRW)	*Diabrotica virgifera virgifera*
Northern corn rootworm (NCRW)	*Diabrotica barberi*
Mexican corn rootworm (MCRW)	*Diabrotica virgifera zeae*

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: __/__/__

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn

(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡

(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1)... ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ..... ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ should be sown on the same day, or with the shortest window possible between

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)	*Ostrinia nubilalis*
Southwestern corn borer (SWCB)	*Diatraea grandiosella*
Southern cornstalk borer (SCSB)	*Diatraea crambidoides*
Corn earworm (CEW)	*Helicoverpa zea*
Fall armyworm (FAW)	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Lesser corn stalk borer	*Elasmopalpus lignosellus*
Sugarcane borer (SCB)	*Diatraea saccharalis*
Western bean cutworm (WBC)	*Richia albicosta*
Black cutworm	*Agrotis ipsilon*
Western corn rootworm (WCRW)	*Diabrotica virgifera virgifera*
Northern corn rootworm (NCRW)	*Diabrotica barberi*
Mexican corn rootworm (MCRW)	*Diabrotica virgifera zeae*

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: __/__/__

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn

(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡

(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1)... ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ..... ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ should be sown on the same day, or with the shortest window possible between

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)	*Ostrinia nubilalis*
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Corn earworm (CEW)	*Helicoverpa zea*
Fall armyworm (FAW)	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
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Sugarcane borer (SCB)	*Diatraea saccharalis*
Western bean cutworm (WBC)	*Richia albicosta*
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MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: __/__/__

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn

(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡

(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1)... ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ..... ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

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MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ should be sown on the same day, or with the shortest window possible between

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

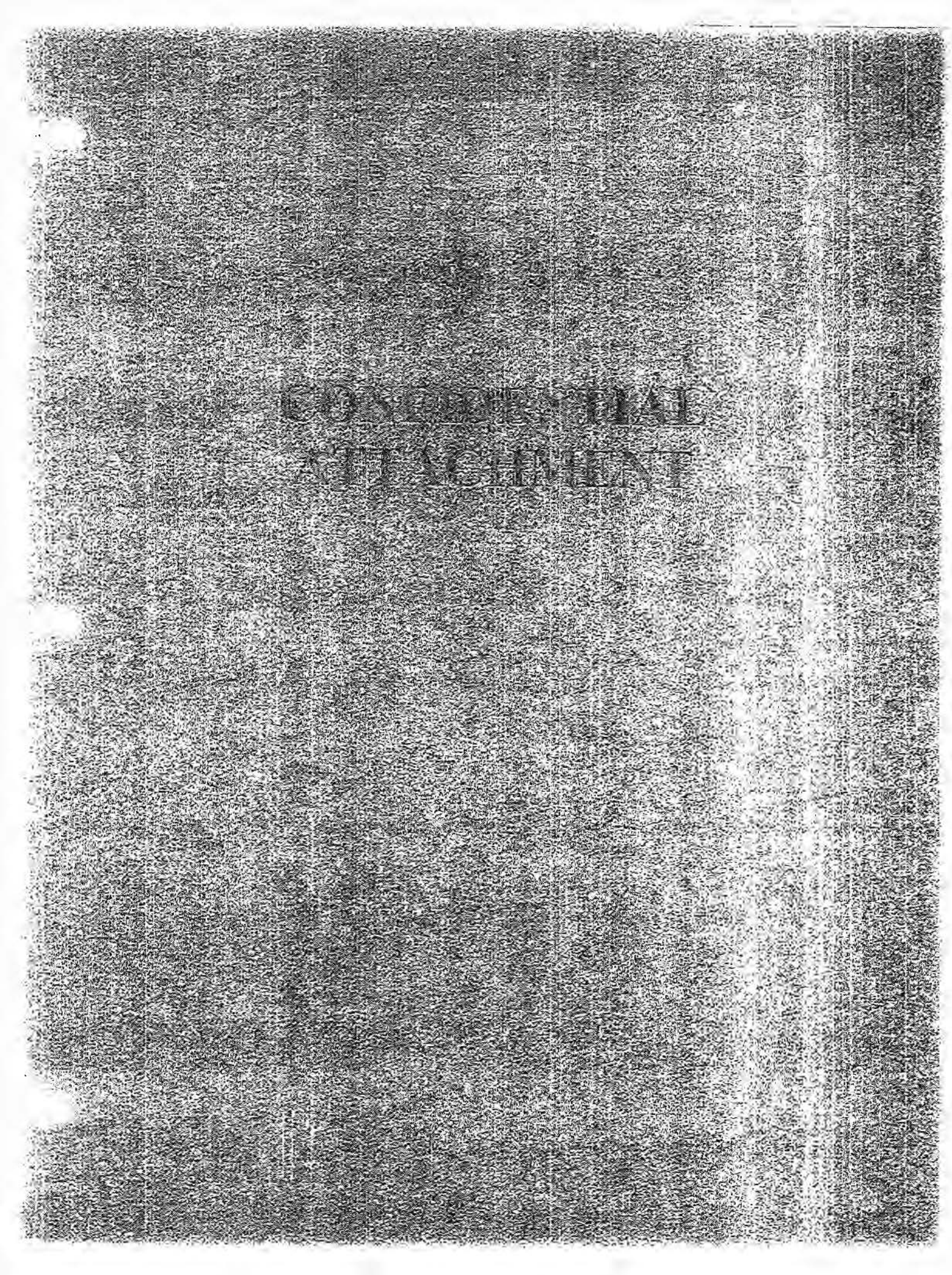
The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)	*Ostrinia nubilalis*
Southwestern corn borer (SWCB)	*Diatraea grandiosella*
Southern cornstalk borer (SCSB)	*Diatraea crambidoides*
Corn earworm (CEW)	*Helicoverpa zea*
Fall armyworm (FAW)	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Lesser corn stalk borer	*Elasmopalpus lignosellus*
Sugarcane borer (SCB)	*Diatraea saccharalis*
Western bean cutworm (WBC)	*Richia albicosta*
Black cutworm	*Agrotis ipsilon*
Western corn rootworm (WCRW)	*Diabrotica virgifera virgifera*
Northern corn rootworm (NCRW)	*Diabrotica barberi*
Mexican corn rootworm (MCRW)	*Diabrotica virgifera zeae*

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: __/__/__



Pages 118-128 - * Claimed confidential by submitter*

MONSANTO
imagine

J. Austin Burns
Regulatory Affairs Manager
(314) 694-6514

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
http://www.monsanto.com

June 10, 2011

Document Processing Desk (PETN)
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application to extend the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™; EPA Registration Number 524-595; non-PRIA.

Dear Dr. Reilly:

Please find an application for the registration extension of the plant-incorporated protectant MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ Insect Protected, Herbicide-Tolerant Corn (EPA Reg. No. 524-595) enclosed.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ was conditionally registered on April 8, 2011. The initial time-limited registration expires on October 31, 2011. During the initial registration period, Monsanto, in conjunction with Dow AgroSciences (EPA Reg. No. 68467-16), are providing further information supporting this product in accordance with the terms and conditions of registration, including an updated draft label. This current application request is to extend EPA Reg. No. 524-595 for a period of two years beyond the current expiration date based on the EPA's registration decision in the BRAD for this product (EPA Docket ID EPA-HQ-OPP-2011-0362-0002, April 8, 2011; p27). A subsequent registration extension will be requested at that time, based on the revised registration duration scheme for PIP products representing reduced risk for developing insect resistance (Optimum® AcreMax™ B.t. Corn Seed Blends BRAD; August 4, 2010; p19). An updated data matrix is being supplied with this application. With the exception of the revised label to incorporate bag-tag language suitable for both the corn- and cotton-growing areas as required under the current terms and conditions, no other changes are being made to the registration conditions as part of this registration extension request, and a timely review and decision is therefore requested.

™ RIB Complete is a trademark of Monsanto Technology LLC

Pursuant to this request, attached is a letter from Dow AgroSciences authorizing data citation related to Events TC1507 and DAS-59122-7.

The documents accompanying this submission are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.

- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

- Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

A CD-ROM containing the fully releasable ("A") documents, with the exception of the data citation authorization letter, is provided in .pdf format.

It is Monsanto's understanding that this request is a non-PRIA action.

- Fee category: Non-PRIA Amendment
- Fee category amount: $0

Documents accompanying this application for registration

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√	√
N/A	A	Dow AgroSciences data citation letter	√	
N/A	A	Transmittal document	√	√
1	B	Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture	√	
1	C	Confidential Statement of Formula	√	

Should you require any additional information regarding this application please feel free to contact Daniel Jenkins at 202-383-2851, or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.
Regulatory Affairs Manager
Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD
Russell Schneider, Monsanto
Nicholas Storer, Dow AgroSciences
Stephanie Burton, Dow AgroSciences

Dow AgroSciences, LLC
9330 Zionsville Road
Indianapolis, IN 46268-1054

Dow AgroSciences

May 27, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Keith Matthews, Esq., Director Biopesticide and Pollution Prevention Division

LETTER AUTHORIZING DATA CITATION

We hereby confirm that Agrigenetics, Inc. d/b/a Mycogen Seeds c/o Dow AgroSciences LLC, on behalf of itself and its affiliates, (collectively, "Dow AgroSciences") authorizes Monsanto Company (Monsanto) to cite, and the U.S. Environmental Protection Agency (EPA) to refer to, data previously submitted by Dow AgroSciences in connection with any of the following products:

- *Insect-protected, glufosinate-tolerant maize containing the Cry1F and PAT proteins, Event TC1507 (DAS-01507-1);*
- *Insect-protected, glufosinate-tolerant maize containing the Cry34/35Ab1 and PAT proteins, Event DAS-59122-7 (DAS-59122-7)*

and all relevant data that Dow AgroSciences has provided EPA to support the Section 3 registration extension for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Insect-Protected, Herbicide-Tolerant Corn (Refuge Advanced™ Powered by SmartStax® / Genuity® SmartStax® RIB Complete™), EPA Registration Nos. 68467-16 and 524-595.

This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any application submitted by any other applicant, for an application by Monsanto for activities other than the registration request as described herein, or for any other regulatory entity to refer to or rely on this data. Dow AgroSciences does not grant permission for citation or reference of this data for any use not specifically stated herein, does not grant permission for citation or reference of data (including future data) not specified herein, and nothing in this agreement grants permission for the U.S. EPA to provide copies of any data to any party.

If you require further information, please contact the undersigned at 317-337-3692.

Best Regards,

Gregory L. Orr, Ph.D.
Global Regulatory Leader – Corn Traits
Dow AgroSciences LLC

SmartStax® multi-event technology developed by Dow AgroSciences and Monsanto.
®SmartStax is a registered trademark of Monsanto Technology LLC.

MONSANTO

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Registration Number: 524-595

TRANSMITTAL DATE

June 10, 2011

MONSANTO REFERENCE No.

11-CR-192E-2R

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1. Administrative Materials for the Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

MRID Number _____

Company Official: _____ 6-10-2011

J. Austin Burns, Ph.D. Date
Regulatory Affairs Manager
(314) 694-6514

Company Name: Monsanto Company

Company Contact: Daniel Jenkins, J.D., M.S.
U.S. Agency Regulatory Affairs Manager
(202) 383-2851

Ms. Stephanie Burton
Associate Biotech Regulatory Manager
Mycogen Seeds c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, Indiana 46268-1054

Subject: Refuge Advanced™ Powered by SmartStax®
June 1, 2011 Application to Amend the Expiration Date
EPA Registration Nos. 68467-16

Dear Ms.Burton:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that the revised expiration date for this product is November 30, 2011. Per our discussions with Dow AgroSciences, the Agency intends to determine a longer term expiration date for this product, along with other SmartStax related products, during the month of November. In order to facilitate this process, please submit a corresponding amendment application.

Sincerely,

Sheryl K. Reilly, Ph.D.
Chief, Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

MONSANTO

VOLUME 1

Administrative Materials for the Application to Amend the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Reg. Number: 524-595

AUTHORS

Bradley A. Comstock
J. Austin Burns, Ph.D.

SUBMISSION DATE

June 10, 2011

SUBMITTING REGISTRANT

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

MONSANTO REFERENCE No.

11-CR-192E-2R

The text below applies only to use of the data by the United States Environmental Protection Agency (U.S. EPA) in connection with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

STATEMENT OF DATA CONFIDENTIALITY CLAIM

No claim of data confidentiality is being made for information contained in this document on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). However, a supplemental data confidentiality claim is being made for some information claimed herein. The applicable information has been removed to a confidential attachment.

"We submit this material to the United States Environmental Protection Agency specifically under requirements set forth in FIFRA as amended, and consent to use and disclosure of this material by the EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 86-5, we reserve and do not waive any rights involving this material that are or can be claimed by the company notwithstanding this submission to the EPA."

COMPANY: Monsanto Company

COMPANY AGENT: _____

J. Austin Burns, Ph.D.
Regulatory Affairs Manager

DATE: June 10, 2011

GLP COMPLIANCE STATEMENT

The materials in this volume do not meet the requirements of the Good Laboratory Practice Standards, 40 CFR Part 160. This volume provides the administrative materials for the Application to amend the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect Protected, Herbicide-Tolerant Corn with an interspersed in-field refuge configuration using a seed mixture, and therefore were not developed in compliance with 40 CFR Part 160.

6-10-2011

Submitter
J. Austin Burns, Ph.D.
Regulatory Affairs Manager

Date

6-10-11

Sponsor
Jeffrey T. Bookout, M.S., M.B.A.
Corn Regulatory Affairs Lead

Date

6/10/11

Study Director
Bradley A. Comstock
Regulatory Affairs Manager

Date

VOLUME 1

TABLE OF CONTENTS

Page

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
File Symbol 524-595	Dr. Sheryl Reilly	☒ None ☐ Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	PM # 92	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167
☐ Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☒ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application.
☐ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Application to Amend the Registration of the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture, to extend registration 524-595

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	(Specify)

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container	Various	☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
☐ Lithograph ☐ Other
☐ Paper glued
☐ Stenciled

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Daniel J. Jenkins, J.D., M.S.	U.S. Agency Regulatory Affairs Manager	(202) 383-2851

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title	5. Date
Typed Name: J. Austin Burns, Ph.D. Tel. (314) 694-6514	Regulatory Affairs Manager	June 10, 2011

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow Applicant Copy

CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S. W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:	EPA Registration Number / File Symbol:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 (314) 694-6514	524-595
Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7	Date: June 10, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature	Date	Typed or Printed Name and Title
J. Austin Burns	June 10, 2011	J. Austin Burns, Ph.D. Regulatory Affairs Manager

EPA Form 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

DATA MATRIX

Date: June 1, 2011	EPA Reg. No./File Symbol: 524-595	Page 1 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MDN 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for the Application to Amend the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture		Monsanto Company	OWN	Administrative This Submission
NA	Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010.	484234-00	Monsanto Company	OWN	Administrative Supporting Data
NA	Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010.	484234-01	Monsanto Company	OWN	Supporting Data
NA	Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	48394001	Monsanto Company	OWN	Supporting Data
NA	Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)	N/A	Monsanto Company	OWN	Supporting Data

Signature	Name and Title	Date
SIGNATURE PAGE FOR 66 PAGES J. Burns	J. Austin Burns, Ph.D. Regulatory Affairs Manager	June 1, 2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Date: June 1, 2011	EPA Reg. No./File Symbol: 524-595	Page 2 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
NA	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture	47943700	Monsanto Company	OWN	Administrative
NA	Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	47943701	Monsanto Company	OWN	Supporting Data
NA	The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn	47943702	Monsanto Company	OWN	Benefits

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See Page 1 for Signature	J. Austin Burns, Ph.D. Regulatory Affairs Manager	June 1, 2011

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Date: June 1, 2011	EPA Reg. No./File Symbol: 524-581	Page 3 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Goodwin, B.K., Marra, M.C., and N.E. Piggott. 2009. Farm-Level Benefits of a Refuge Reduction for SmartStax ™. A report from Agri-Analytics, Inc.	N/A	Monsaato Company	OWN	Supporting Information
	Burns, J.A. 2009. The Benefits of Refuge Reduction to 5% for SmartStax Corn	47943702	Monsanto Company	OWN	Supporting Information
	Burns, J.A. 2009. Response to U.S. EPA BPPD Letter, Dated March 19, 2009 Regarding Applications to Register MON 89034 ×TC1507 × MON 88017 × DAS-59122-7 EPA File Symbols: 524-LIR (MON); D-395123 (DAS).	N/A	Monsanto Company	OWN	Supporting Information
	Bogdanova, N., J.A. Burns, G. Head, et. al. 2009. Condition of Registration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn: Compliance Assurance Plan	47883601	Monsanto Company	OWN	Terms and Conditions
	Bogdanova, N., J. Cardea, J. Lambert, et. al. 2009. Educational Materials and Information of IRM Requirements Provided by Monsanto Company to Growers of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn	47883602	Monsanto Company	OWN	Terms and Conditions

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G., W. Moar, and N. Storer. 2009. Insect Resistance Monitoring and a Remedial Action Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn	47883603	Monsanto Company	OWN	Terms and Conditions
	Keller, P. 2011. Annual Sales Report for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7	48367801	Monsanto Company	OWN	Terms and Conditions
	Submission of Pesticide Use Data in Support of the Registrations of MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034 (× NK603), MON 89034 × MON 88017, MON 89034 × TC1507 × MON 88017 × DAS-59122-7	48367800	Monsanto Company	OWN	Terms and Conditions
	Zahora, A. and P. Keller. 2011. 2010 Insect Resistance Management Compliance Assurance Program Report for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-protected and Herbicide Tolerant Corn	48367901	Monsanto Company	OWN	IRM
	Submission of Efficacy Data in Support of the Registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7	48369700	Monsanto Company	OWN	Product Characterization

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Date: June 1, 2011	EPA Reg. No./File Symbol: 524-581	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G., M. Carroll, L. Stork, et. al. 2011. Corn Rootworm Adult Emergence from MON 89034 × TC1507 × MON 88017 × DAS-59122-7, MON 88017, DAS-59122-7, and Non-Bt Corn with Various Egg Densities in 2010 U.S. Field Trials	48369701	Monsanto Company	OWN	IRM
	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34 and Cry35 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7.		Monsanto Company	OWN	Administrative
885.1100	Burns, J.A. 2008. Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins Produced in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021223.	47444901	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F. 2008. Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021265.	47444902	Monsanto Company	OWN	Product Characterization
885.1100	Taylor, J.P., J.R Groat, and J.D. Masucci. 2007. Southern Blot Analyses to Confirm the Presence of MON 89034 and MON 88017 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0020682.	47444903	Monsanto Company	OWN	Product Characterization

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Schafer, B.W., C.Q. Cia, and S.K. Embrey. 2008. Southern Blot Analyses to Confirm the Presence of TC1507 and DAS-59122-7 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Dow AgroSciences Study ID 071179.	47444904	Monsanto Company	OWN	Product Characterization
885.1100	Murphy, J.A. and J.S. McClain. 2008. Summary of Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Produced in US Field Trials in 2006. Monsanto Technical Report MSL0021266.	47444905	Monsanto Company	OWN	Product Characterization
885.1100	Stillwell, L. and A. Silvanovich. 2007. Assessment of Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021070.	47444906	Monsanto Company	OWN	Production Characterization
885.1100	Phillips, A.M. 2008. Cry34Ab1, Cry35Ab1, Cry1F, and PAT Protein Levels in Hybrid Maize TC1507, DAS-59122-7, MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and a Conventional Control from the Monsanto 2006 Production Plan 06-01-52-04. Dow AgroSciences Study ID 061026.06.	47444907	Monsanto Company	OWN	Product Characterization
N/A	Levine, S. 2008. Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021267.	47444908	Monsanto Company	OWN	Environmental Assessment

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	MacRae, T. 2008. Evaluation of Potential for Interaction Between the *Bacillus thuringiensis* Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins. Monsanto Technical Report MSL0020554.	47444909	Monsanto Company	OWN	Environmental Assessment
N/A	Levine, S. 2008. Evaluation of the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7 by Insect Bioassay. Monsanto Technical Report MSL0021104.	47444910	Monsanto Company	OWN	Environmental Assessment
N/A	Head, G. and N. Storer. 2008. Insect Resistance Management Plan for MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021285.	47444911	Monsanto Company	OWN	IRM
N/A	Levine, S. and J. Huesing. 2008. Endangered Species Impact Assessment for the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021268.	47444912	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M. 2008. Evaluation of Potential Dietary Effects of Pollen From the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on the Ladybird Beetle *Coleomegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL 0021036.	47444913	Monsanto Company	OWN	Environmental Assessment

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Date: June 1, 2011	EPA Reg. No./File Symbol: 524-575	Page 8 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Updated Compliance Assurance Plan, Educational Materials, IRM Monitoring, and a Remedial Action Plan for MON 89034 (EPA Reg. No. 524-575) and MON 89034 × MON 88017 (EPA Reg. No. 524-576) Insect-Protected and Herbicide-Tolerant Corn	483696-01	Monsanto Company	OWN	Terms & Conditions
	Annual Sales Report for MON 810, MDN 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7 (EPA Reg. Nos. 524-489, 524-528, 524-545, 524-551, 524-552, 524-575, 524-576, and 524-581)	483678-01	Monsanto Company	OWN	Terms & Conditions
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm-Protected Bt Corn, and Corn Borer / Corn Rootworm Protected Stacked Bt Corn.	483751-01	ABSTC	OWN	Terms & Conditions
	Baseline Assessment of Bt Susceptibility of Corn Earworm, *Helicoverpa zea*, to Cry1A.105; 2009 Collections and Assays (Lang, B. 2010)	48207401	Monsanto Company	OWN	IRM-Condition of Registration
	Baseline Susceptibility of the European Corn Borer, *Ostrinia nubilalis*, to Cry1A.105 and Cry2Ab2 Bt Proteins (Siegfried, B. and Spencer, T. 2010)	48207402	Moasanto Company	DWN	IRM-Condition of Registration
	2010 Insect Resistance Management Compliance Assurance Program Report for Corn Borer Protected Bt Corn MON 89034 (EPA Reg. No. 524-575)		Monsanto Company	OWN	IRM-Condition of Registration

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Baseline Susceptibility of Southwestern Corn Borer, *Diatraea grandiosella*, to Cry1A.105 and Cry2Ab2 Bt Proteins (Song, Q., Sun, Y. and Wang, Q. 2009)	48207403	Monsanto Company	OWN	IRM-Condition of Registration
	Annual Sales report for MON 810 (EPA Reg.No. 524-489), MON 863 (EPA Reg. No. 524-528), MON 863 x MON 810 (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), MON 89034 (EPA Reg. No. 524-575) and MON 89034 x MON 88107 (EPA Reg. No. 524-576)	479614-01	Monsanto Company	OWN	Terms & Conditions
	Updated Compliance Assurance Plan, Educational Materials, IRM Monitoring, and a Remedial Action Plan for MON 89034 and MON 89034× MON 88017 Insect-Protected and Herbicide-Tolerant Corn (Keller, P. 2011)	479033501	Monsanto Company	OWN	Conditions of Registration
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	471275-03	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Company	OWN	Product Characterization

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient: *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.	469514-01	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.R. Groat, N.K. Scanlon, J.C. Jennings, and J.D. Mastucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	469514-02	Monsanto Company	DWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Monsanto Company	OWN	Product Characterization
885.1100	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and *E. coli*-Produced Cry2Ab2 Proteins. Monsanto Technical Repon MSL-20071.	469514-04	Monsanto Company	OWN	Product Characterization

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in *E.Coli* and *Bt* Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	469514-05	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Mascuci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068	466945-01	Monsanto Company	OWN	Product Characterization
885.1100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the Cry1A.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and *E.coli*-Produced Cry1A.105 Proteins. Monsanto Technical Report MSL-19960.	466946-04	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	471275-03	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Company	OWN	Product Characterization

Signature	Name and Title	Date
See Page 1 for Signature	J. Austin Burns, Ph.D. Regulatory Affairs Manager	June 1, 2011

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the Cry1A.105 Protein to Cry1A Class of *Bacillus thuringiensis* Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsanto Company	OWN	Product Characterization
860.1340	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsanto Company	OWN	Product Characterization
885.3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.	469514-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the *in vitro* Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	469514-07	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S. and E.A. Rice. 2005. Assessment of the *in vitro* Digestibility of the Cry1A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	469514-08	Monsanto Company	OWN	Human Health Assessment

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Date: June 1, 2011	EPA Reg. No./File Symbol: 524-575	Page 13 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the Cry1A.105 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Thorp, J.J. and M.E. Goley. 2006. Assessment of the *in vitro* Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938	469514-09	Monsanto Company	OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cry1A.105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.	469514-10	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the *in vitro* Digestibility of the Cry1A.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	466946-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and Cry1A.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	466946-07	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with Cry1A.105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Company	OWN	Human Health Assessment

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	469514-11	Monsanto Company	OWN	Human Health Assessment
885.4050	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Control or Commercial Corn. Monsanto Study 05-01-50-13, Amended Report.	469514-12	Monsanto Company	OWN	Human Health Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of *Bacillus thuringiensis* Cry1A.105 Protein. Monsanto Technical Report MSL-20230.	469514-13	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of *Bacillus thuringiensis* Cry2Ab2 Protein. Monsanto Technical Report MSL-20229.	469514-14	Monsanto Company	OWN	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	469514-15	Monsanto Company	OWN	Environmental Assessment

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (*Folsomia candida*). Monsanto Technical Report MSL-20169.	469514-16	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran *Daphnia magna*: An acute static-renewal test with corn pollen. Monsanto Study WL-2005-01t.	469514-17	Monsanto Company	OWN	Environmental Assessment
885.6200	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-20147.	469514-18	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Honeybee Larvae (*Apis mellifera* L.). Monsanto Study CA-2005-071.	469514-19	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Adult Honeybees (*Apis mellifera* L.). Monsanto Study CA-2005-072	469514-20	Monsanto Company	OWN	Environmental Assessment

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, *Coleomegilla maculato* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.	469514-21	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, *Coleomegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.	469514-22	Monsanto Compaay	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, *Orius insidiosus* (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20170.	469514-23	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, *Orius insidiosus* (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20171.	469514-24	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, *Ichneumon promissorius* (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149.	469514-25	Monsanto Company	OWN	Environmental Assessment

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.	469514-27	Monsanto Company	OWN	Environmental Assessment
885.5200	Mueth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.	469514-28	Monsanto Company	OWN	Environmental Assessment
N/A	Hnesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the *Bacillus thuringiensis* Proteins Cry1A.105 and Cry2Ab2. Monsanto Technical Report MSL-19859.	466946-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, *Ichneumon promissorius* (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Monsanto Company	OWN	Environmental Assessment

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Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.J. and H.O. Krueger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-16177	450863-13	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified *Bacillus thuringiensis* Cry2Ab2 protein on honey bee larvae. Monsanto Technical Report MSL-16961.	453371-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (*Folsomia candida*), Amended report. Monsanto Technical Report MSL-16174.	450863-14	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (*Nasonia vitripennis*). Monsanto Technical Report MSL-16173.	450863-10	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (*Apis mellifera* L.). Monsanto Technical Report MSL-16176.	450863-08	Monsanto Company	OWN	Environmental Assessment

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Date: June 1, 2011	EPA Reg. No./File Symbol: 524-575	Page 19 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034	

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.	469514-30	Monsanto Company	OWN	IRM
	Bogdanova, N. and A. Crawford (2007). Public Interest Document Supporting Registration of *Bacillus thuringiensis* Cry1A.105 , Cry2Ab2 and Cry3Bb1 Proteins in Insect-Protected Corn MON 89034 and MON 89034 x MON 88017	472797-01	Monsanto Company	OWN	Benefits
	Bogdanova, N., S. Dubelman, M. Mueth, J. Murphy and A. Silvanovich (2007). Responses to EPA Questions Regarding Application 524-LTL to register Insect-Protected Corn MON 89034 (MRID 46951428)	471403-01	Monsanto Company	OWN	Misc.
	Bogdanova, N. , (2007) Responses to EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	471275-01	Monsanto Company	OWN	Misc.
	Bogdanova, N.., (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	470794-02	Monsanto Company	OWN	Misc.

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Date: June 1, 2011	EPA Reg. No./File Symbol: 68467-2	Page 20 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	
Ingredient: *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Acute oral toxicity in mice: Cry1F *Bacillus thuringiensis* subsp. aizawai delta endotoxin	44691101	68467	PER	
	Effectiveness data for *Bacillus thuringiensis* var. aizawai Cry1F insect control protein as expressed in maize	44691102	68467	PER	
	Background document on resistance management	44691103	68467	PER	
	Product Characterization Data for *Bacillus thuringiensis* var. aizawai Cry1F Insect Control Protein as expressed in Maize	44714801	68467	PER	
	Characterization of Gene Inserts-*Bacillus thuringiensis* var. aizawai Cry1F Insect Control Proteins Expressed in Maize	44714802	68467	PER	
	Equivalency of Microbial and Maize Expressed Cry1F Protein; Characterization of Test Substances for Biochemical and Toxicological Studies. In Vitro Digestibility of Microbial and Maize Expressed Cry1F Protein Under Simulated Gastric Conditions	44714803	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Quantitative ELISA Analysis of Cry1F Expression levels in Maize MPS Inbred Lines 1360, 1365, 1366, and 1369. (Interim Report)	44714804	68467	PER	
	Comparison of Amino Acid Sequence Similarity of Cry1F and PAT Proteins to Known Allergen Protein	44971701	68467	PER	
	Microbial B.t. Cry1F (truncated) Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study	45020101	68467	PER	
	Characterization of inserted genes in Cry1F maize line 1507	45020102	68467	PER	
	Effectiveness Data for *Bacillus thuringiensis* var. aizawai Cry1F Insect Control Protein as Expressed in Maize	44691102	68467	PER	
	Characterization of Expressed Cry1F Protein in Maize Tissues (Pollen, Grain, Grain-Containing Feed, and Purified Maize-Expressed Cry1F Protein) and Microbial Expressed Cry1F Delta Endotoxin by Biological and Biochemical Procedures	45020103	68467	PER	
	Quantitative ELISA Analysis of Cry1F and PAT Expression levels in and Compositional Analysis of Maize Inbred and Hybrid Lines 1362 and 1507	45020104	68467	PER	

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Date: June 1, 2011	EPA Reg. No./File Symbol: 68467-2	Page 22 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Environmental Fate of Cry1F Protein incorporated into Soil	45020105	68467	PER	
	Cry1F *Bacillus thuringiensis* var. aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	45020106	68467	PER	
	Chronic exposure of *Folsomia candida* to bacterially expressed Cry1F protein	45020107	68467	PER	
OECD 202	*B.t.* Cry1F delta endotoxin: A 48-hour static-renewal acute toxicity test with the Cladoceran (*Daphnia magna*) using bacterially expressed *B.t.* Cry1F delta endotoxin, and pollen from maize expressing *B.t.* Cry1F delta endotoxin	45020108	68467	PER	
885.4340	Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary study with green lacewing larvae	45020109	68467	PER	
885.4340	Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary study with the ladybird beetle	45020110	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Cry1F *Bacillus thuringiensis* var. aizaiwai delta endotoxin: A dietary toxicity study with parasitic hymenoptera	45020111	68467	PER	
71-2	Transgenic corn expressing *Bacillus thuringiensis* var. aizawai (*B.t.*) Cry1F delta endotoxin: A dietary toxicity study with Northern bobwhite	45020112	68467	PER	
	Field survey of beneficial arthropods associated with *Bacillus thuringiensis* Cry1F maize	45020113	68467	PER	
	Efficacy of Cry1F events TC1360 and TC1507	45020114	68467	PER	
	Cry1F binding studies	45020115	68467	PER	
	Resistance management plan for transgenic maize expressing the Cry1F insecticidal protein from *Bacillus thuringiensis* var. aizaiwai	45020116	68467	PER	

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Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 44714801: Supplemental data - Product characterization data for *Bacillus thuringiensis* var. aizawai: Cry1F control protein as expressed in maize	45020117	68467	PER	
	Supplement to MRID 44691101: Supplemental data - Acute oral toxicity in mice: *Bacillus thuringiensis* var. aizawai Cry1F delta endotoxin	45020118	68467	PER	
	Phosphinothricin acetyltransferase (PAT) protein: In vitro digestibility study	45041501	68467	PER	
	Non-target exposure and risk assessment for environmental dispersal of Cry1F maize pollen	45041502	68467	PER	
	Evaluation of the dietary effect(s) on honeybee development using bacterially expressed *B.t.* Cry1F delta endotoxin and pollen from maize expressing *B.t.* Cry1F delta endotoxin	45041503	68467	PER	
	Waiver request: Fish toxicity test with transgenic maize (corn) containing *Bacillus thuringiensis* var. aiaqoi (*B.t.*) Cry1F delta endotoxin	45044201	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	
Ingredient: *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	High dose demonstration of Cry1F events TC1360 and TC1507: European corn borer	45131101	68467	PER	
	Toxicity of the Cry1F protein to neonate larvae of the monarch butterfly (*Danaus plexippus* (Linneaus))	45131102	68467	PER	
	Public interest document for Cry1F-protected corn	45131103	68467	PER	
	Thermolability of Cry1F (truncated) delta endotoxin	45274801	68467	PER	
	Compositional analysis of maize MPS hybrid line 1507	45274802	68467	PER	
	Cry1F lateral flow test kit procedure for analyzing Cry1F corn grain	45279301	68467	PER	
	Method validation report for the determination of Cry1F delta endotoxin protein in grain by Enzyme-Linked Immunosorbent Assay	45279302	68467	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I *Insect Protection*	
Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 45131102: Supplemental data - High dose demonstration of Cry1F events TC1360 and TC1507: European corn borer	45307701	68467	PER	
	Waiver request: Fish toxicity test to assess the potential effects of maize containing *Bacillus thuringiensis* var. aizawai (Bt) Cry1F insecticidal protein (ICP) in native fish	45307702	68467	PER	
	Supplement to MRID 45020109: Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary toxicity study with green lacewing larvae	45307801	68467	PER	
	Supplement to MRID 45020110: Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary toxicity study with green ladybird beetle	45307802	68467	PER	
	Supplement to MRID 45020111: Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: A dietary toxicity study with parasitic hymenoptera	45307803	68467	PER	
	Supplement to MRID 45020106: Cry1F *Bacillus thuringiensis* var. aizawai delta endotoxin: An acute toxicity study with the earthworm in an artificial soil substrate	45307804	68467	PER	

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Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 45041503: Evaluation of the dietary effect(s) on honeybee development using bacterially expressed *B.t.* Cry1F delta endotoxin and pollen from maize expressing *B.t.* Cry1F delta endotoxin	45307805	68467	PER	
	Exposure and risk assessment of Herculex I Bt field corn pollen to Kamer blue butterfly	45512901	68467	PER	
	Nutritional equivalency of *B.t.* Cry1F maize - poultry feeding study	45622001	68467	PER	
	Field survey of beneficial arthropods associated with *Bacillus thuringiensis* Cry1F maize	45648001	68467	PER	
	Field surveys of non-target invertebrate populations in *B.t.* corn	45652001	80778	PER	
	Development and characterization of Enzyme-Linked Immunosorbent Assay (ELISA) for detection of Cry1F protein	45685601	68467	PER	

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Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Independent laboratory validation of method GRM 02.13, determination of Cry1F delta endotoxin protein in corn grain by an of Enzyme-Linked Immunosorbent Assay	45685602	68467	PER	
	Supplement to MRID 45131102: Toxicity of the Cry1F protein to neonate larvae of the monarch butterfly (*Danaus plexippus* (Linneaus))	45759701	68467	PER	
	Stewardship of Herculex I Insect Protection with respect to the secondary lepidopteran pest, western bean cutworm (*Richia albicosta* Smith)	45896501	68467	PER	
	Lack of cross reactivity between Cry1F protein in Herculex I maize and the dust mite Der p7 protein with human sera positive for Der p7-IgE	46444001	68467	PER	
	Monitoring the susceptibility of European corn borer to Cry1Ab and Cry1F Bt proteins: Results from the 2004 collections and diapausing larvae collected in 2003	46583101	80778	PER	
	Stewardship of event TC1507 maize with respect to the secondary lepidopteran pests lesser corn stalk borer (*Elasmopalpus lignosellus* Zeller), southern corn stalk borer (*Diatraea crambidioides* Grote), and sugarcane borer (*Diatraea saccharalis* Fabricius)	46600201	68467	PER	

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Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Slide presentation summarizing European corn borer and Cry1F resistance monitoring update	46695801	68467	PER	
	Insect resistance management compliance assurance program report for corn borer-protected Bt corn	46747801	80778	PER	
	Field surveys of non-target invertebrate populations in Bt corn: Supplement to MRID No. 45652001	46784601	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2005 monitoring results	46874901	80778	PER	
	Research results on 2004 European corn borer collections from Hamilton County, Iowa: Cry1F	47011201	68467	PER	
	Insect resistance management compliance assurance program report for corn borer-protected Bt corn, corn rootworm-protected Bt corn, and corn borer/corn rootworm protected stacked Bt corn	47044401	80778	PER	

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Ingredient: *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD identifier: DAS-Ø15Ø7-1)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2006 monitoring results	47118401	80778	PER	
	Soil accumulation of Cry1F after three years of cropping with Herculex I corn	47120701	68467	PER	
	TC1507 maize and fall armyworm in Puerto Rico	47176001	68467	PER	
	Proposed revisions to IRM-related registration requirements for Cry1 plant-incorporated protectants in field corn	47407001	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2007 monitoring results	47413901	80778	PER	
	Proposed revisions to IRM-related registration requirements for Cry1 plant-incorporated protectants in field corn	47543901	80778	PER	

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Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2008 monitoring results	47841801	80778	PER	
	Monitoring the susceptibility of corn lepidopteran pests to Cry1Ab and Cry1F proteins: 2009 monitoring results	47971001	80778	PER	
	Production Report and Certificate of Analysis of Truncated Cry1F (TSN104550)	48193001	68467	PER	
	2010 Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375001	80778	PER	
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375101	80778	PER	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017	

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Conditions of Registration for MON 88017 (EPA Reg. No.524-551) and MON 89034 x MON 88017 (EPA Reg. No.524-576), and Response to EPA's Request for Additional Information on Monsanto's Resistance Corn Rootworm (CRW) Monitoring Program.	484368-01	Monsanto Company	OWN	Terms & Conditions
	Conditions of Registration for MON 88017 (EPA Reg. No. 524-551) and Conditions of Registration for MON 89034 x MON 88017 (EPA Reg. No. 524-576).	484368-01	Monsanto Company	OWN	Terms & Conditions
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm-Protected Bt Corn, and Corn Borer / Corn Rootworm Protected Stacked Bt Corn.	483751-01	ABSTC	PER	Terms & Conditions
	Annual Sales Report for MON 810, MON 863, MON 863 × MON 810, MON 88017, MON 88017 × MON 810, MON 89034, MON 88017 × MON 89034, and MON 88017 × MON 89034 × TC1507 × DAS-59122-7 (EPA Reg. Nos. 524-489, 524-528, 524-545, 524-551, 524-552, 524-575, 524-576, and 524-581).	483678-01	Monsanto Company	OWN	Terms & Conditions
	2009 Season Monitoring for the susceptibility of Neonate Western Corn Rootworm Larvae to the *Bacillus thuringiensis* Cry3Bb1 Protein.	N/A	Monsanto Company	OWN	Terms & Conditions
	2009 Season Monitoring for the Susceptibility of Neonate Western Corn Rootworm Larvae to the *Bacillus thuringiensis* Cry3Bb1 Protein.	482080-01	Monsanto Company	OWN	Terms & Conditions

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017	

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	2009 Insect Resistance Management Compliance Assurance Program Report for Corn Borer-Protected Bt Corn (EPA Reg. Nos. 524-489, 68467-2, 67979-1, and 29964-3), Corn Rootworm-Protected Bt Corn (EPA Reg. Nos. 524-528, 524-551, 68467-5, 67979-5, and 29964-4), and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn (EPA Reg. Nos. 524-545, 524-552, 524-576, 68467-6, 67979-8, and 29964-5).	479710-01	ABSTC	PER	Terms & Conditions
	Annual Sales report for MON 810 (EPA Reg.No. 524-489), MON 863 (EPA Reg. No. 524-528), MON 863 x MON 810 (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), MON 89034 (EPA Reg. No. 524-575) and MON 89034 x MON 88107 (EPA Reg. No. 524-576).	479614-01	Monsanto Company	OWN	Terms & Conditions
	2008 Season Monitoring for the Susceptibility of Neonate Western Corn Rootworm Larvae to the *Bacillus thuringiensis* Cry3Bb1 Protein.	478846-01	Monsanto Company	OWN	Terms & Conditions
	2008 Insect Resistance Management Compliance Assurance Program Report for Corn Borer-Protected Bt Corn (EPA Reg. Nos. 524-489, 68467-2, 67979-1, and 29964-3), Corn Rootworm-Protected Bt Corn (EPA Reg. Nos. 524-528, 524-551, 68467-5, 67979-5, and 29964-4), and Corn Borer/Corn rootworm-Protected Stacked Bt Corn (EPA Reg. Nos. 524-545, 524-552, 68467-6, 67979-8, and 29964-5).	476633-01	ABSTC	PER	Terms & Conditions

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017	

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Annual Sales Report for YieldGard Corn Borer Corn (EPA Reg. No. 524-489), YieldGard Rootworm Corn (EPA Reg. No. 524-528), YieldGard Plus Corn (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551), and MON 88017 × MON 810 (EPA Reg. No. 524-552).	476631-01	Monsanto Company	OWN	Terms & Conditions
	2006 Insect Resistance Management Compliance Assurance Program for Corn Borer-Protected Bt Corn, Corn Rootworm-Protected Bt Corn and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn. (ABSTC Report).	470444-01	ABSTC	PER	Terms & Conditions
	Submission of Annual Sales Report for YieldGard® Corn Borer corn (EPA Reg. No. 524-489), YieldGard® Rootworm corn (EPA Reg. No. 524-528), YieldGard® Plus corn (EPA Reg. No. 524-545), MON 88017 (EPA Reg. No. 524-551) and MON 88017 x MON 810 (EPA Reg. No. 524-552), (2007).	470431-01	Monsanto Company	OWN	Terms & Conditions
	Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 toxin from *Bacillus thuringiensis*: 2005 Data Summary.	469491-01	Monsanto Company	OWN	Terms & Conditions

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry3Bb1 Protein Produced in MON 88017. MSL-18835	461817-01	Monsanto Company	OWN	Product Characterization
885.1100	Beasley, K. A., H.M. Anderson., P.B. Wimberley, D.W. Mittank., and R.P. Lirette. (2002). Molecular analysis of YieldGard®Rootworm/Roundup Ready®Corn Event MON 88017. MSL-17609	461817-02	Monsanto Company	OWN	Product Characterization
885.1100	Bhakta, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002. MSL-18823	461817-03	Monsanto Company	OWN	Product Characterization
885.1100	Duan, J. J., M. S. Paradise and C. Jiang (2003). Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran species. MSL-18799	461817-04	Monsanto Company	OWN	Product Characterization
885.1100	Hileman, R. E. and J. D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in MON 863. MSL-17137	454240-10	Monsanto Company	OWN	Product Characterization

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Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E., G. Hollenschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by *E. coli* Fermentation and MON 863. MSL-17274	455382-01	Monsanto Company	OWN	Product Characterization
860.1340	Brown, M. (2003). *TraitChek*™ Cry3Bb Lateral Flow Test Strip and *SeedChek*™ Cry3Bb ELISA Performance Verification for Corn Seed, Leaf, and Composite Testing. MSL-19581, in unpublished study conducted by Strategies Diagnostics, Inc.	463942-01	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y. A., B-P. Tonnu, L. D. Albee and R. P. Lirette (2001). Amended Report for MSL-16559: *B.t.* Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. MSL-17181	454240-01	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran Species" (MRID No. 461817-04)	465783-03	Monsanto Company	OWN	Product Characterization
885.1100	Thuma, R. S., G. Hollenschak, R. E. Hileman and J. D. Astwood (2001). Primary Structural Protein Characterization of MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154	454240-11	Monsanto Company	OWN	Product Characterization

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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Submission of Supplemental Data (May 21, 2001) in Support of the Application for Registration of MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI.	N/A	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y., B-P. Tonnu and R. P. Lirette (2001). Cry3Bb1, Cry1Ab and NPTII Protein Levels in the Dual-trait Maize Hybrid MON 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. MSL-17266	457917-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of *B.t.* Protein 11098, *B.t.* Protein 11231 and NPTII Protein Expressed in Corn Events MON 853 and MON 860 to Microbial Sources. MSL-17222	454240-04	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002" (MRID No. 461817-03)	465783-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.11098 and NPTII Proteins in Corn Event MON 863 to Microbial Sources. MSL-17220	454240-05	Monsanto Company	OWN	Product Characterization

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Supplemental Information for "Molecular Analysis of YieldGard® Rootworm/Roundup Ready® Corn Event MON 88017" (MRID No. 461817-02)	465783-01	Monsanto Company	OWN	Product Characterization
860.1340	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Hoesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. Monsanto Ref. No. 99-640E-1.	453731-01	Monsanto Company	OWN	Product Characterization
N/A	Astwood, J. .D., R. E. Hileman, M. J. McKee, T. J. Rydel, J. W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225	454240-09	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the *in vitro* Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530	455770-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment. MSL-17223	454240-07	Monsanto Company	OWN	Human Health Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3050	Beehtel, C. L. (1999). Acute Oral Toxicity of *B.t.* Protein 11231 in Mice. MSL-16216.	449043-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140	454240-08	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Mice with *E. coli* Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382	455382-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman and J. D. Astwood (2001). Assessment of the *in vitro* Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from *E. coli*. MSL-17292	455382-03	Monsanto Company	OWN	Human Health Assessment
885.3050	Beehtel, C. L. (1999). Acute Oral toxicity of *B.t.* Protein 11098 in Mice. MSL-16215	449043-06	Monsanto Company	OWN	Human Health Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of *B.t.* Protein 11098 and *B.t.* Protein 11231 Sequences Utilizing Toxin and Public Domain Genetic Databases. MSL-15870	449043-08	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of *B.t.* Protein 11098 and *B.t.* Protein 11231 Sequences Utilizing an Allergen Database. MSL-15873	449043-09	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the *In Vitro* Digestibility of *B.t.* protein 11098 and *B.t.* 11231 Utilizing Mammalian Digestive Fate Models. MSL-17166	454240-06	Monsanto Company	OWN	Human Health Assessment
885.4200	McKee, M. J. (2001). Bluegill Dietary Toxicity Study for the *Bacillus thuringiensis* Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383	455382-00	Monsanto Company	OWN	Environmental Assessment
885.4240 Series 72, Subdivision E	Drottar, K. R. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (*Daphnia magna*). MSL-16163	449043-18	Monsanto Company	OWN	Environmental Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4280	Results of acute toxicity tests with *Daphnia* and catfish did not produce any evidence of adverse effects. Estuarine and Marine animal studies are waived for this product because of the very low to no potential for exposure to Cry3Bb1 protein from field corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Texiera, D. (2005). Evaluation of Dietary Effects of a Cry3Bb1 Protein Variant on Minute Pirate Bugs (*Orius insidiosus*). MSL-19697	464799-05	Monsanto Company	OWN	Environmental Assessment
885.4300	Since the active ingredient in this product is an insect toxin (Bt endotoxin) that has never shown any toxicity to aquatic or terrestrial plants, these studies have been waived for this product. The Agency has determined there is no significant risk of gene capture and expression of Cry3Bb1 protein by wild or weedy relatives of corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Palmer, S. J. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (*Hippodamia convergens*). MSL-16166	449043-14	Monsanto Company	OWN	Environmental Assessment
850.6200	Hoxter, K. A., S. J. Palmer and H. O. Krueger (1999). *Bacillus thuriagiensis* Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162	449043-16	Monsanto Company	OWN	Environmental Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the *Bacillus thuringiensis* Protein 11098 to Collembola (*Folsomia candida*). MSL-15988	449043-17	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11231: A Dietary Study with Green Lacewing Larvae (*Chrysoperla carnea*). MSL-16165	449043-12	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. D. Krueger (1999). *Bacillus thuringiensis* Protein 11231: A Dietary Study with the Parasitic Hymenoptera (*Nasonia vitripennis*). MSL-16167	449043-13	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., M. Bhatti, B. Ayden, J. Murphy, S. Levine and C. Jiang (2005). Environmental Fate of Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-19285	465103-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic *Bacillus thuringiensis* (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, *Coleomegilla maculata*. MSL-16936	453613-01	Monsanto Company	OWN	Environmental Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Bryan, R. L., J. R. Porch and H. O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, *Hippodamia convergens*. MSL-17171	453613-02	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179	455382-06	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., M. J. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic *Bacillus thuringiensis* (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, *Coleomegilla maculata*. MSL-16907	455382-04	Monsanto Company	OWN	Environmental Assessment
885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (*Danus plexippus*) via Laboratory Bioassay. MSL-17235	455382-05	Monsanto Company	OWN	Environmental Assessment
N/A	Head, G., M. Pleau, S. Sivasupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein *in vitro*. C3NTO	455382-07	Monsanto Company	OWN	Environmental Assessment

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017	

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MON 863. MSL-17614	455770-03	Monsanto Company	OWN	Environmental Assessment
154-2300	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. Monsanto Reference No. 00-CR-032E-7	456530-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., J. D. Duan, C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Report MSL-17531	457916-01	Monsanto Company	OWN	Environmental Assessment
850.6200	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137	457571-01	Monsanto Company	OWN	Environmental Assessment
885.4050	Gallagher, S. P., J. Grimes and J. B. Beavers (1999). *Bacillus thuringiensis* Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161	449043-15	Monsanto Company	OWN	Environmental Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V. L. (1999). Evaluation of the Dietary Effect(s) of Purified *Bacillus thuringiensis* Protein 11231 on Adult Honey Bees (*Apis mellifera* L.). MSL-16169	449043-11	Monsanto Company	OWN	Environmental Assessment
885.5200	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudin (2000). Aerobic Soil Degradation of the *B.t.* Protein 11098 as a Component of Insect Protected Corn. MSL-16440	451568-04	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the *Bacillus thuringiensis* Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected MON 863. MSL-17102	457571-02	Monsanto Company	OWN	Environmental Assessment
885.4050	George, B. (2001). Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. MSL-17243	459415-01	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified *Bacillus thuringiensis* Protein 11231 on Honey Bee Larvae. MSL-16168	449043-10	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, J. Colyer, B. Ledesma, S. Levine, F. Lloyd, G. Mueller, J. Warren & C. Jiang (2007) Environmental Fate of the Cry3Bb1 and Cry1Ab Proteins in Corn Fields Planted with MON 863 x MON 810 for Three Consecutive Years MSL-20589	472829-02	Monsanto Company	OWN	Environmental Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-3500	Duan, J., M. Bhatti, C. Brown, G. Head, C. Jiang, C. Pilcher, C. Pilcher, D. Carson & T. Nickson (2007) Two Year Field Assessment of the Effect of Combined Trait Bt Corn Mon 863 x MON 810. MSL-19696	472829-01	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, M.J. McKee, M.A. Nemeth, D. Ward, G. Head, S. Levine, M. Bhatti and M. Paradise (2004). Statistical Power Analysis of a Two-Year Field Study Evaluating the Ecological Effect of Corn Event MON 863. MSL-19246	462627-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, C. Brown, M. Bhatti, M. Nemeth, T. Nickson and D. Ward (2004). Supplemental Statistical Analysis of Data from a Two-Year Field Census Study with Corn Event MON 863. MSL-19329	463942-02	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman S., M. Bhatti and B. Ayden (2004). Interim Report: Assessment of the Environmental Fate of the Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-18931	462001-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan J. and M. Paradise (2005). Evaluation of Dietary Effects of Cry3Bb1 Protein on the Ground Beetle *Poecilus chalcites* (Coleoptera:Carabidae). MSL-19631	464799-04	Monsanto Company	OWN	Environmental Assessment
154-3500	Head, G. (2004). Research on the Effects of Corn Rootworm Protected Transgenic Corn on Non-Target Organisms: Publications & Manuscripts.	462627-02	Monsanto Company	OWN	Environmental Assessment

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4150	Mammalian wildlife exposure to Cry3Bb1 protein is considered likely; however, the Cry3Bb1 toxicity data for Human Health Assessment indicate that there is no significant toxicity to rodents form testing at the maximum hazard dose. Therefore no hazard to mammalian wildlife is anticipated.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4200	Li, M. H. and E. H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164	449043-19	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003). Data Waiver Request: Toxicity of *B.t.* Cry3Bb1 Protein in the Red Milkweed Beetle (*Tetraopes* sp.). MSL-18741	N/A	Monsanto Company	OWN	Environmental Assessment Granted in BRAD
N/A	Pilcher, C. D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments – Results of Year 2000 Field Trials. Monsanto Ref. No. 00-CR-032E-3	453613-03	Monsanto Company	OWN	Benefits
N/A	Mitchell, P. D. (2002). Yield Benefit of MON 863. MSL-17782	456530-02	Monsanto Company	OWN	Benefits

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in MON 863. MSL-17766	456530-01	Monsanto Company	OWN	Benefits
N/A	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR12L, ZMIR13L and ZMIR14L). Monsanto Ref. No. 99-781E	450297-01	Monsanto Company	OWN	Benefits
N/A	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - YieldGard® Rootworm. MSL-17993	456923-01	Monsanto Company	OWN	Benefits
N/A	Vaughn, T. T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (*Diabrotica barberi*), Southern Corn Rootworm (*D. undecimpunctata howardi*), and Western Corn Rootworm (*D. virgifera virgifera*). MTC RPT4	455382-08	Monsanto Company	OWN	Benefits
N/A	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McPerson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556	455770-01	Monsanto Company	OWN	Benefits/IRM

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Vaughn, T. (2004). Progress Report on Insect Resistance Management for Corn Event MON 863.	461865-01	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	IRM
N/A	Head, G. and K. Reding. (2006). Corn rootworm Insect Resistanee Management Research (fourteen journal publications)	467424-01	Monsanto Company	OWN	IRM
N/A	Davis, P., G. Head, J. McFerson et. al. (2000). Insect Resistance Management for a Transgenic Corn Rootworm Corntrt Product.	451568-05	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4	459438-01	Monsanto Company	OWN	IRM

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	T. Vaughn (2005). Second Progress Report on Insect Resistance Management for Corn Event MON 863. REVISED	N/A	Monsanto Company	OWN	IRM
N/A	Letter submitted May 23, 2003 to EPA with 12 research protocols on the biology and ecology of the corn rootworm pest complex.	N/A	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2004). 2004 Progress Report for the Corn Event MON 863 Resistance Monitoring Program.	462627-01	Monsanto Company	OWN	IRM
N/A	Administrative Materials in Support of the Registration of *Bacillus thuringiensis* Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	451568-00	Monsanto Company	OWN	Tolerance Exemption
N/A	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant *Bacillus thuringiensis* Corn Rootworm Control Protein, as Produced in the Corn (*Zea mays*, L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	449043-00	Monsanto Company	OWN	Tolerance Exemption

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Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Petition for Exemption from the Requirement of a Tolerance for *Bacillus thuringiensis* Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins in or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients.	PP 7F4888	Monsanto Company	OWN	Tolerance Exemption
885.1100	McCoy, R. L. and A. Sivanovich (2003). Bioinformatics Analysis of the CP4 EPSPS Protein Utilizing the AD4, TOXINS and ALLPEPTIDES Databases. MSL18752	466361-01	Monsanto Company	OWN	Inert Ingredient
885.1100	McCoy, R.L. and A. Sivanovich (2005). Updated Bioinformatics Evaluation of the CP4 EPSPS Protein Utilizing the AD5 Database. MSL19894	466361-02	Monsanto Company	OWN	Inert Ingredient
885.3050	Monsanto Company (1995). Submission of Toxicology Data in Support of a Tolerance Petition for CP4 EPSPS as a Plant Pesticide Formulation Inert Ingredient: Transmittal of 1 Study.	436919-00	Monsanto Company	OWN	Inert Ingredient
885.3050	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgette (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12: 92-419-719	436919-01	Monsanto Company	OWN	Inert Ingredient

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885.1100	Padgette, S., G. Barry, D. Re, D. Eichholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-enolpyruvylshikimate-3-phosphate Synthase from *Agrobacterium sp.* Strain CP4. MSL-12738	438076-01	Monsanto Company	OWN	Inert Ingredient
885.1100	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant *Escherichia coli* Fermentation. MSL-12389	438076-02	Monsanto Company	OWN	Inert Ingredient
885.1100	Heeren, R., S. Padgette and M. Gustafson (1993). The Purification of Recombinant *Escherichia coli* CP4 5-enolypyruvylshikimate-3-phosphate synthase for Equivalence Studies. MSL-12574	438076-03	Monsanto Company	OWN	Inert Ingredient
N/A	Monsanto Company (1995). Submission of Product Chemistry, Toxicology and Pesticide Fate in Animals Data in Support of the Exemption for the Requirement of a Petition for Tolerance for CP4 EPSPS. Transmittal of 4 studies.	436433-00	Monsanto Company	OWN	Inert Ingredient
885.1100	Harrison, L., M. Bailey, R. Leimgruber, C. Smith, D. Nida, M. Taylor, M. Gustafson, B. Heeren and S. Padgette (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPS. Lab Project Number: 92/01/30/14: 12901	436433-01	Monsanto Company	OWN	Inert Ingredient

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885.1100	Lee, T., M. Bailey, C. Smith, J. Zeng, E. Elswick and P. Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in *Escherichia coli* and European Corn Borer Resistant Corn. Lab Project Number: 94-01-39-10: MSL-13920	436433-02	Monsanto Company	OWN	Inert Ingredient
885.3050	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92223	436433-03	Monsanto Company	OWN	Inert Ingredient
885.1100	Ream, J., M. Bailey, J. Leach and S. Padgette (1993). Assessment of the in vitro Digestive Fate of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949	436433-04	Monsanto Company	OWN	Inert Ingredient
N/A	Revisions and Clarification to the Terms & Conditions of Registration for Corn Event MON 863 and YieldGard® Plus Corn; Progress Report on Multiple IRM-Related Activities for MON 863; and Response to EPA Letter Dated August 13, 2004. Submitted 7/7/2005.	N/A	Monsanto Company	OWN	Terms & Conditions
N/A	Siegfried, B. and T. Spencer (2005). Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 Toxin from *Bacillus thuringiensis*. This report satisfies the Insect Monitoring Terms & Conditions.	467259-01	Monsanto Company	OWN	Terms & Conditions

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW *Insect Protection*	

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product characterization data for *Bacillus thuringiensis* PS149B1 13.6 kDa and 43.8 kDa insecticidal crystal proteins expressed in transgenic maize plants	45242201	68467	PER	
	Equivalency of microbial and maize-expressed PS149B1 proteins	45242203	68467	PER	
	Microbial PS149B1 Binary Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study	45242204	68467	PER	
	Comparison of the Amino Acid Sequence of the *Bacillus thuringiensis* Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Allergens	45242205	68467	PER	
	Characterization of *Pseudomonas* produced and transgenic maize expressed phosphinothricin acetyltransferase (PAT) protein	45242206	68467	PER	
	PS149B1 14 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242207	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242208	68467	PER	
	PS149B1 14 KDA and 44 KDA Proteins: Acute Oral Toxicity study in CD-1 Mice	45242209	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: A Dietary Toxicity Study with the Ladybird Beetle	45242210	68467	PER	
	The Tri-Trophic Interaction Between PS149B1 Transformed Maize, Corn Leaf Aphid and Ladybird Beetle	45242211	68467	PER	
	In Vitro Digestibility of PS149B1 Proteins	45242212	68467	PER	
	Quantitative ELISA analysis of PS149B1 protein expression levels in hybrid and inbred lines of maize event TC5639 (interim report)	45242213	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Degradation of Microbial Binary PS149B1 Delta-Endotoxin in a Representative Soil from the Mid-Western USA Maize-Growing Region	45242214	68467	PER	
	Product durability plan for transgenic maize expressing insecticidal crystal protein from *Bacillus thuringiensis* strain PS149B1 during the experimental use period	45242215	68467	PER	
	Field efficacy of PS149B1 maize events against corn rootworms	45242216	68467	PER	
	Microbial PS149B1 Binary Insecticidal Crystal Protein, Pollen Expressing PS149B1 Binary Insecticidal Crystal Protein, and Individual PS149B1 14kDa and 44 kDa Insecticidal Crystal Proteins	45340701	68467	PER	
	Thermolability of PS149B1 Binary Delta-Endotoxin	45358401	68467	PER	
	PS149B1 binary insecticidal crystal protein: Acute toxicity study to the earthworm in an artificial substrate	45360201	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Lateral flow test kit method validation for the detection of the PS149B1 14 kDa and 44 kDa protein in maize grain	45383401	68467	PER	
	Heat lability of individual proteins of the PS149B1 binary ICP	45584501	68467	PER	
	In Vitro Simulated Gastric Fluid Digestibility Study of Microbially Derived Cry34Ab1 Protein	45584502	68467	PER	
	Characterization of Cry34Ab1 and Cry35Ab1 from Recombinant *Pseudomonas fluorescens* and Transgenic Maize	45790401	68467	PER	
	Characterization of DNA Inserted into Transgenic Corn Events (Cry34Ab1 and Cry35Ab1)	45790402	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, *Oncorhynchus mykiss*, Walbaum	45790403	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Daphnid, *Daphnia magna* Straus	45790404	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera (*Nasonia vitripennis*)	45790405	68467	PER	
	Assessment of Chronic Toxicity of Diet Containing *Bacillus thuringiensis* PS149B1 Insecticidal Crystal Protein to Collembola (*Folsomia candida*)	45790406	68467	PER	
	PS149B1 Insecticidal Crystal Protein: Dietary Toxicity to Green Lacewing Larvae (*Chrysoperla carnea*)	45790407	68467	PER	
	SDS-PAGE Sensitivity Analysis for Cry35Ab1 in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212	45790408	68467	PER	
	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Ab1 and Cry35Ab1	45790509	68467	PER	
	Field Efficacy of Cry34Ab1/Cry35Ab1 Maize Events Against Corn Rootworms	45790410	68467	PER	
	Product characterization data for *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins expressed in transgenic maize plants (PHP17658)	45790501	68467	PER	
	Product Characterization Data for *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 Proteins Expressed in Transgenic Maize Plants (PHP17662)	45790601	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Summary of Heat Lability Studies with Cry34Ab1/Cry35Ab1	45808601	68467	PER	
	Quantitative ELISA analysis of Cry34Ab1 and Cry35Ab1 proteins expressed in maize plants transformed with the vector PHP17658	45833101	68467	PER	
	Quantitative ELISA analysis of Cry34Ab1 and Cry35Ab1 proteins expressed in maize plants transformed with the vector PHP17662	45833102	68467	PER	
	Quantitative ELISA Analysis of Cry34Ab1 and Cry35Ab1 Proteins Expressed in Maize Plants Transformed with the Vector PHP17662	45833201	68467	PER	
	Slide Presentation Summarizing Cry34Ab1/Cry35Ab1 Heat Inactivation Studies.	45860201	68467	PER	
	Probe MOA studies to assess potential for protein synthesis inhibition by *Bacillus thuringiensis* PS149B1 Cry34Ab1/Cry35Ab1 proteins in rabbit reticulocyte assay: Re-examination of lab notebook data	45942801	68467	PER	
	Product characterization data for *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins expressed in transgenic maize plants (PHP17662)	46030001	68467	PER	
	Independent Laboratory Validation Pioneer Hi-Bred International, Inc. ELISA Method for the Quantitification of Cry34Ab1Protein from Transgenic Plants	46123901	68467	PER	
	Independent Laboratory Validation of Dow AgroSciences Method GRM 03.13, "Determination of Cry35Ab1 Insecticidal Crystal Protein in Maize Tissue by Enzyme-Linked Immunosorbent Assay"	46123902	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cry34/35 Protein Distribution and Familiarity	46123903	68467	PER	
	Agronomic Characteristics, Quantitative ELISA and Nutrient Composition Analysis of Hybrid Maize Lines Containing Cry34Ab1, Cry35Ab1 and PAT Genes: Chile Locations	46123904	68467	PER	
	Biological equivalency of Cry34/35Ab1 insecticidal crystal protein in transgenic plants and derived from transgenic *Pseudomonas fluorescens*	46123905	68467	PER	
	Characterization of Cry34Ab1 and Cry35Ab1 Proteins Derived from Transgenic Maize event E4497.59.1.22 (DAS-59122-7)	46123906	68467	PER	
	Characterization of Phosphinothricin Acetyltransferase (PAT) Derived from Transgenic Maize Event E4497.59.1.22	46123907	68467	PER	
	Characterization of DNA Inserted into Transgenic Corn Events DAS-45216-6 and DAS-59122-7	46123908	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Detailed characterization of DNA inserted into transgenic corn events DAS-45216-6 and DAS-59122-7	46123909	68467	PER	
	Evaluation of microbe derived Cry34Ab1 and Cry35Ab1 proteins for protein synthesis inhibition activity	46123910	68467	PER	
	Nutritional Equivalency Study of Maize Containing Cry34Ab1 and Cry35AB1: Poultry Feeding Study	46123911	68467	PER	
	The effect of Cry34Ab1/Cry35Ab1 proteins on the development and mortality of the Ladybird beetle *Coleomegilla maculata* DeGeer	46123912	68467	PER	
	Non-target Invertebrate Ecological Risk Assessment for Field Corn Expressing Cry34Ab1 and Cry35Ab1 Insecticidal Crystal Proteins in Event DAS-59122	46123913	68467	PER	
	Evaluation of the impact of corn rootworm control strategies on non-target arthropods	46123914	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Investigations into Dose of Cry34Ab1/Cry35Ab1 Rootworm-Resistant Maize Event DAS-59122-7 Against Western and northern Corn Rootworms in Support of Trait Durability Plans	46123915	68467	PER	
	Effect on Western Corn Rootworm Adults of Feeding on Cry34/35Ab1-Corn Rootworm Protected Corn Tissue and Implications for Product Durability	46123916	68467	PER	
	Evaluation of endangered/threatened insect species relative to the use of Cry34Ab/Cry35Ab1 corn rootworm-resistant maize hybrids	46123917	68467	PER	
	Trait Durability Plan for Cry34/35 Corn Rootworm Protected corn Event DAS-59122-7 Following Commercialization	46123918	68467	PER	
	Simulations of Corn Rootworm Adaptation to Cry34/35 Corn Rootworm Protected Corn in Support of Trait Durability Plans for Event DAS-59122-7	46123919	68467	PER	
	Digestion of Allergenic and Non-Allergenic Proteins in Simulated Gastric Fluid	46123920	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Public Interest Document for Cry34/35Ab1 Corn Rootworm-Protected Corn	46123921	68467	PER	
	Investigation of Potential Interaction between Cry1F and the Binary Cry34Ab1/Cry35Ab1 Proteins	46343806	68467	PER	
	Digestion efficiency of allergens and non-allergens in simulated gastric fluid: *Bacillus thuringiensis* Cry 34/35Ab1 construct PHP17662	46388601	68467	PER	
	Lack of Cry34Ab1/Cry35Ab1 co-association in solution	46556801	68467	PER	
	Evaluation of the Sequence Similarities of the Cry34Ab1, cry35Ab1, and PAT Proteins to the Public Protein Sequence Datasets	46584701	68467	PER	
	Summary report of a carabid beetle laboratory toxicity study using Cry34Ab1 and Cry35Ab1 including copies of references	46714101	68467	PER	

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	Preliminary resistance monitoring plan for Cry34/35Ab1 corn event DAS-59122-7	46769201	68467	PER	
	Detailed resistance monitoring plan for Cry34/35Ab1 corn event DAS-59122-7	47334201	68467	PER	
	Evaluation of potential dietary effects of Cry34/35Ab1 protein on insidious flower bugs, *Orius insidiosus* (Hemiptera: Anthocoridae)	47436701	68467	PER	
	Monitoring corn rootworm susceptibility to Cry34/35Ab1 event DAS-59122-7: 2007 insect collections	47522501	68467	PER	
	Three-Year Field Monitoring of Cry34/35Ab1 and Cry1F x Cry34/35Ab1 Maize Hybrids for Nontarget Arthropod Effects	47870301	68467	PER	
	Monitoring corn rootworm susceptibility to Cry34/35Ab1 event DAS-59122-7: 2008 insect collections	47900801	68467	PER	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Soil accumulation of Cry34Ab1 and Cry35Ab1 proteins after three years of cropping with DAS-59122-7 corn	47959501	68467	PER	
	Investigating Performance of Herculex™ RW and Herculex™ XTRA Under Commercial Use	48045501	68467	PER	
	Monitoring Corn Rootworm Susceptibility to Cry34/35Ab1 Event DAS-59122-7: 2009 Growing Season	48279701	68467	PER	
	2010 Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375001	68467	PER	

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DATA MATRIX

Date: June 10, 2011	EPA Reg. No./File Symbol: 68467-5	Page 66 of 66
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® RW *Insect Protection*	

Ingredient *B.t.* Cry34Ab1 and Cry35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Enhanced Insect Resistance Management Compliance Assurance Program for Corn Borer Protected Bt Corn, Corn Rootworm Protected Bt Corn, and Corn Borer/Corn Rootworm-Protected Stacked Bt Corn	48375101	68467	PER	
	Revised Guidelines for Evaluating Unexpected Corn Rootworm Damage in Herculex® RW and Herculex® XTRA	48430701	68467	PER	

Signature	Name and Title	Date
See Page 1 for Signature	J. Austin Burns, Ph.D. Regulatory Affairs Manager	June 1, 2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

SUMMARY OF THE APPLICATION

The subject of this application is for the registration extension of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect Protected, Herbicide-Tolerant Corn (Genuity® SmartStax® RIB Complete™; EPA Reg. No. 524-595).

Genuity® SmartStax® RIB Complete™ was conditionally registered on April 8, 2011. The initial time-limited registration expires on October 31, 2011. This current application request is to extend EPA Reg. No. 524-595 for a period of two years beyond the current expiration date based on the EPA's registration decision in the BRAD for this product (EPA Docket ID EPA-HQ-OPP-2011-0362-0002, April 8, 2011; p27). A subsequent registration extension will be requested at that time, based on the revised registration duration scheme for PIP products representing reduced risk for developing insect resistance (Optimum® AcreMax™ B.t. Corn Seed Blends BRAD; August 4, 2010; p19). An updated data matrix is being supplied with this application. With the exception of the revised label to incorporate bag-tag language suitable for both the corn- and cotton-growing areas as required under the current terms and conditions, no other changes are being requested to the registration conditions as part of this registration extension request.

™ RIB Complete is a trademark of Monsanto Technology, LLC.

® Genuity and SmartStax are registered trademarks of Monsanto Technology, LLC.

PRODUCT LABEL

The subject of this application is for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™. No substantive changes to the label for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Insect-Protected, Herbicide-Tolerant Corn in EPA Reg. No. 524-595, as updated April 8, 2011, are being requested. The patent numbers have been updated. Five copies of the proposed label for the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ are attached.

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7
RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1).. ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ..... ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ should be sown on the same day, or with the shortest window possible between

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)	*Ostrinia nubilalis*
Southwestern corn borer (SWCB)	*Diatraea grandiosella*
Southern cornstalk borer (SCSB)	*Diatraea crambidoides*
Corn earworm (CEW)	*Helicoverpa zea*
Fall armyworm (FAW)	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Lesser corn stalk borer	*Elasmopalpus lignosellus*
Sugarcane borer (SCB)	*Diatraea saccharalis*
Western bean cutworm (WBC)	*Richia albicosta*
Black cutworm	*Agrotis ipsilon*
Western corn rootworm (WCRW)	*Diabrotica virgifera virgifera*
Northern corn rootworm (NCRW)	*Diabrotica barberi*
Mexican corn rootworm (MCRW)	*Diabrotica virgifera zeae*

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: __/__/__

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1).. ≤ 0.0012%*

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Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

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Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

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Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do **not** apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

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The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

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In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

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KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

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The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ should be sown on the same day, or with the shortest window possible between

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)	*Ostrinia nubilalis*
Southwestern corn borer (SWCB)	*Diatraea grandiosella*
Southern cornstalk borer (SCSB)	*Diatraea crambidoides*
Corn earworm (CEW)	*Helicoverpa zea*
Fall armyworm (FAW)	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Lesser corn stalk borer	*Elasmopalpus lignosellus*
Sugarcane borer (SCB)	*Diatraea saccharalis*
Western bean cutworm (WBC)	*Richia albicosta*
Black cutworm	*Agrotis ipsilon*
Western corn rootworm (WCRW)	*Diabrotica virgifera virgifera*
Northern corn rootworm (NCRW)	*Diabrotica barberi*
Mexican corn rootworm (MCRW)	*Diabrotica virgifera zeae*

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: __/__/__

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7
RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS-Ø15Ø7-1).. ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ..... ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ or comparable information presented on the product bag or bag-tag, must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-Bt seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for Genuity® SmartStax® RIB Complete™ satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, Genuity® SmartStax® RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of Genuity® SmartStax® RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ should be sown on the same day, or with the shortest window possible between

planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of Genuity® SmartStax® RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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Stalk borer	*Papaipema nebris*
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MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5550318, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7112665, 7227056, 7250501, 7304206, 7544862, 7618942, 7927598, and RE39247.

EPA Accepted: __/__/__

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7
RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-I × MON-88ØI7-3 × DAS-59122-7)

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*Maximum percent (wt/wt) of dry forage

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KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

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Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag, on planting, production, and insect resistance management, and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

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EPA Accepted: __/__/__

CONFIDENTIAL ATTACHMENT

Pages 237 247 - * Claimed confidential by submitter*

MONSANTO

FOR IMMEDIATE RELEASE

MONSANTO U.S. MEDIA CONTACT | Ben Kampelman (314-694-6192)

Monsanto Completes U.S. Regulatory Registration for Genuity® SmartStax® RIB Complete™
Plans Set to Introduce Industry's First, Single-Bag Refuge Solution for Corn

ST. LOUIS (April XX, 2011) — U.S. farmers in the Corn Belt can now choose the simplicity, convenience and refuge compliance benefits of the industry's first, single-bag refuge solution for corn. Genuity® SmartStax® RIB Complete™ by Monsanto Company (NYSE: MON) has received registration from the U.S. Environmental Protection Agency. This completes federal regulatory authorization in the United States. Commercialization is pending individual state authorizations and notifications, as required.

The product is the outcome of a collaboration between Monsanto and Dow AgroSciences LLC, a wholly owned subsidiary of The Dow Chemical Company. It is a combination of each company's industry-leading corn traits that provide farmers with multiple modes-of-action for broad spectrum control of above- and below-ground insects, and also offers two herbicide tolerance traits for flexible weed management. Today's registration of Genuity SmartStax RIB Complete provides farmers with the opportunity to plant a single-bag refuge solution for corn.

Genuity SmartStax RIB Complete is a blend of 95 percent Genuity SmartStax corn seed and 5 percent refuge (non-*Bt*) seed that farmers can plant across their entire field. This means that farmers who plant Genuity SmartStax RIB Complete products no longer need to plant a separate, structured refuge for above- or below-ground pests in the Corn Belt. For farmers who have purchased Genuity SmartStax without the RIB Complete, the structured refuge is still required.

"We're committed to developing products that help improve farmers' productivity. Farmers have told us they want a true, single-bag refuge solution, and this registration enables Monsanto to deliver," said Brett Begemann, Monsanto Executive Vice President and Chief Commercial Officer. "For farmers planting a field of Genuity SmartStax RIB Complete corn, we've simplified refuge management by eliminating the structured refuge, which can contribute to timely, more efficient planting and on-farm productivity."

2012 Full Commerciol Launch Remoins On-Track

With the registration now in-hand, Monsanto confirms that it expects a full commercial launch in more than 100 seed brands in 2012. The company also expects Genuity SmartStax RIB Complete will be available in demonstration quantities in 2011 through Monsanto's national and regional seed brands, as well as through a limited number of licensing partners, primarily in the northern Corn Belt.

"This is a product that will truly simplify the management of my operation and improve my peace-of-mind at the same time," said Greene, Iowa, farmer Ron Litterer. "In order to be refuge compliant on my

Genuity SmartStax RIB Complete fields, all I'll have to do is tear open the bag and pour the seed into my planter. That will allow me to plant the most traited acres in every field, while complying with refuge requirements."

In corn farming, a refuge is an integral component of insect resistance management. The refuge provides a shelter for insects susceptible to *Bt* technology so that any rare individual insects that survive after feeding on *Bt* corn can mate with susceptible insects and produce susceptible offspring. This preserves *Bt* technology that helps corn plants protect themselves from insect pests.

For downloadable audio, photographs and more, please visit the press kit on Monsanto's website.

About Monsanto

Monsanto Company is a leading global provider of technology-based solutions and agricultural products that improve farm productivity and food quality. Monsanto remains focused on enabling both small-holder and large-scale farmers to produce more from their land while conserving more of our world's natural resources such as water and energy. To learn more about our business and our commitments, please visit: www.monsanto.com. Follow our business on Twitter® at www.twitter.com/MonsantoCo, on Facebook® at www.facebook.com/MonsantoCo, or subscribe to our News Release RSS Feed.

Editors note: Monsanto corn seed brands and licensees in the Northern Corn Belt that are expected to have Genuity SmartStax RIB Complete product commercially available in 2011 include national brands DEKALB and Channel; regional brands Fontanelle, Gold Country Seed, Heritage, Hubner Seed, Jung, Kruger, Lewis, Reo, Specialty, Stewart, Stone Seed Group and Trelay Seeds; and also licensees of Monsanto's seed technology.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
524-595	APR 08 2011

Term of Issuance: Conditional

NOTICE OF PESTICIDE:
_x_ Registration
___ Reregistration
(under FIFRA, as amended)

Name of Pesticide Product:
MON 89034 x TC1507 x MON 88017 x DAS-59122-7 RIB Complete Insect Protected, Herbicide-Tolerant Corn

Name and Address of Registrant (include ZIP Code):

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA § 3(c)(7)(A) provided that you do the following terms and conditions

1) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.

2) The subject registration will automatically expire on midnight October 31, 2011.

3) The subject registration is limited to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend in field corn.

4) Submit or cite all data required to support MON 89034 x TC1507 x MON 88017 x DAS-59122-7 plant-incorporated protectant products within the timeframes required by the terms and conditions of EPA Registration Numbers 524-581.

Signature of Approving Official:	Date:
	08-Apr-2011

EPA Form 8570-6

5) Provided the registration expiration date is extended, submit an interim report on the following data within one year and a final report within two years.

- Revised modeling incorporating the structural elements recommended by the SAP (i.e., explicit larval movement, switch from a frequency-based model to one including density-dependent larval mortality, epistatic mechanisms for resistance in target pests) with separate analyses for SWCB and ECB. Non-uniform oviposition should be modeled for both ECB and SWCB, especially (but not only) for the second generation of adults which will more likely lay eggs on Bt rather than on damaged (or crowded out) non-Bt refuge plants in seed blends.

- Biological research on adult movement (related to mating and movement from refuges), larval movement, larval feeding (i.e., selective feeding within corn ears or on pollen), survival of heterozygote genotypes on MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (markers may need to be determined for heterozygotes), and the potential for epistatic mechanisms of resistance (particularly with older instars).

6) Do the following Insect Resistance Management Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn.

a) Refuge Requirements for MON 89034 x TC1507 x MON 88017 x DAS-59122-7

The following information must be included on the product bag or bag-tag as sold per respective region:

Bag or Bag-Tag for the Corn-Growing Region
There are no requirements for a separate structured refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn when planted in the U.S. corn-growing region. The refuge seed of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn is contained in the bag resulting in a refuge configuration that is interspersed within the field. SEE THE IRM/GROWER GUIDE FOR DETAILED IRM REQUIREMENTS, including the areas making up the corn-growing region.

Bag or Bag-Tag for the Cotton-Growing Region
Growers in the cotton-growing region of the U.S. who plant MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn are required to plant an additional 20% structured refuge (i.e. 20 acres of non-*B.t.* corn for every 80 acres of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn planted). The 20% refuge must be planted with corn hybrids that do not contain *B.t.* technologies for the control of corn rootworms or corn borers. The refuge and the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn field. SEE THE IRM/GROWER GUIDE FOR DETAILED IRM REQUIREMENTS, including the areas making up the cotton-growing region.

The cotton-growing region requiring the additional 20% refuge consists of the following states:

Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The following information regarding refuge placement for commercial production must be included in the IRM/Grower Guide:

This product includes refuge that is interspersed within the field by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed. The seed mix refuge option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed blend corn satisfies the refuge requirements in all regions other than in cotton growing regions where corn earworm is a significant pest as defined below.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

Additional refuge requirements in cotton-growing regions where corn earworm is a significant pest

In cotton-growing regions where corn earworm is a significant pest, as defined below, MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed blend corn requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed blend corn planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed blend corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed blend corn field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed blend corn in the refuge exceeds

economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

b) Grower Agreement for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Seed Blend Corn

1) Persons purchasing MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must implement a system (equivalent to what is already approved for previously registered Monsanto *Bt* corn products), which is reasonably likely to assure that persons purchasing *MON* 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description of the system must be submitted to EPA within 90 days from the date of registration.

4) Monsanto must use a grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, 30 days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this registration.

5) Monsanto must implement a system (equivalent to what is already approved for previously registered Monsanto *Bt* corn products), which is reasonably likely to assure that persons purchasing MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn sign grower

agreement(s). A description of the system must be submitted to EPA within 90 days from the date of registration.

6) Monsanto shall maintain records of all MON 89034 x TC1507x MON 88017 x DAS-59122-7 seed blend corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7) Beginning on January 31, 2012 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn seed shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2011 growing season.

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Seed Blend Corn

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn users the importance of complying with the IRM program. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Beginning January 31, 2012, Monsanto must provide a report to EPA summarizing the activities it carried out under its education program for the prior year. Annually thereafter, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Given that MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend will likely have different refuge strategies for lepidoptera and CRW than other registered Bt corn products,

Monsanto must submit a revised compliance assurance program (CAP) within 90 days of the date of registration. This revised CAP must be found acceptable by BPPD by April 1, 2012. This strategy should be specific for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn and the new refuge requirements. Availability of non-Bt corn refuge seeds in desirable varieties must be addressed. Compliance is an area of ongoing concern -- recent data have shown that refuge compliance for Bt corn has fallen in recent years.

d) Insect Resistance Monitoring and Remedial Action Plans for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Corn

Existing programs for resistance monitoring and remedial action for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 are applicable and required for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn. Monsanto must submit a revised definition of unexpected damage in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn for resistance monitoring must also submit a remedial action plan within 90 days of the date of registration that must be found acceptable to BPPD by April 1, 2012.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2012, for the duration of the conditional registration.

e) Annual Reporting Requirements for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Seed Blend Corn

1) Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2012;

2) Grower Agreements: number of units of MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn seed shipped or sold and not returned, and the number of such units that were soldto persons who have signed grower agreements, January 31st each year, beginning in 2011;

3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2012;

4) Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, January 31st each year, beginning in 2012;

5) Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2012;

6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2012.

f) Refuge Assurance Program for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Seed Blend Corn

Monsanto and Monsanto's seed company licensees must continue to implement a blended seed refuge assurance program designed to ensure MON 89034 x TC1507 x MON 88017 x DAS-

59122-7 seed blend corn products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending (Monsanto and Monsanto Licensees)
2. Standard Operating Procedures for the blending process;
3. Calibration of blending equipment; and
4. Records and data retention records for seed blend products.

    - Calibration records – Monsanto and Monsanto's Licensees will retain documentation for three (3) years on the equipment calibration including the procedure, when it was conducted and the results.
    - Blend proportion records (weight and kernel based) – Monsanto and Monsanto Licensees will retain documentation for three (3) years on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn product by seed lot.

All records must be maintained at the Monsanto and Monsanto Licensees blending facility and must be available for the EPA review upon request.

Within one year of the date of registration Monsanto will collect documentation from qualification test runs that validate blend percentages from their licensees/conditioners that produce MON 89034 x TC1507 x MON 88017 x DAS-59122-7 seed blend corn and submit this data to the Agency. Any licensee/conditioner that is unable to verify their blend accuracy will provide evidence demonstrating application and participation in the USDA USA Accredited Seed Conditioning Program (ASCP) as outlined in ARC 1005D Appendix, http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=AccreditedSeedPrograms&rightNav1=AccreditedSeedPrograms&topNav=&leftNav=&page=ASLProgram&resultType=&acct=amdrevcom.

Should Monsanto or Monsanto's Licensees be notified by the USDA/AMS or State Seed Control Officials that your seed blend products have been found to have a lower percentage of the refuge component than is represented on the label, they must notify EPA within 30 days. This would constitute information reportable under FIFRA section 6(a)(2).

6) Monsanto must submit revised product labeling that indicates one seed tag for use in both cotton and non-cotton growing areas within six months.

7) Monsanto must report on how many of their licensees (by number and percentage) color seed January 31st each year, beginning in 2012.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A copy of the stamped label is enclosed for your records.

Sincerely,

Keith A. Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

RIB Complete™

Insect-Protected, Herbicide-Tolerant Corn

(Alternate Brand Name: Genuity® SmartStax® RIB Complete™)‡

(OECD Unique Identifier: MON-89Ø34-3 × DAS- Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ..... ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1).. ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ..... ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)..... ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)..... ≤ 0.0042%*

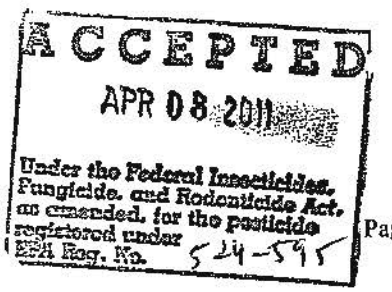
Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ Genuity® SmartStax® RIB Complete™ seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.



KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-~~XXXX~~ 595
EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by an IRM/Grower Guide which includes information on planting, production, and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the IRM/Grower Guide.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The following information must be included on the product bag or bag-tag as sold per respective region:

Bag or Bag-Tag for the Corn-Growing Region

There are no requirements for a separate structured refuge for Genuity® SmartStax® RIB Complete™ corn when planted in the U.S. corn-growing region. The refuge seed of Genuity® SmartStax® RIB Complete™ corn is contained in the bag resulting in a refuge configuration that is interspersed within the field. SEE THE IRM/GROWER GUIDE FOR DETAILED IRM REQUIREMENTS, including the areas making up the corn-growing region.

Bag or Bag-Tag for the Cotton-Growing Region

Growers in the cotton-growing region of the U.S. who plant Genuity® SmartStax® RIB Complete™ corn seed are required to plant an additional 20% structured refuge (i.e. 20 acres of non-*B.t.* corn for every 80 acres of Genuity® SmartStax® RIB Complete™ corn planted). The 20% refuge must be planted with corn hybrids that do not contain *B.t.* technologies for the control of corn rootworms or corn borers. The refuge and the Genuity® SmartStax® RIB Complete™ corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the Genuity® SmartStax® RIB Complete™ corn field. SEE THE IRM/GROWER GUIDE FOR DETAILED IRM REQUIREMENTS, including the areas making up the cotton-growing region.

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The following information regarding refuge placement for commercial production must be included in the IRM/Grower Guide:

This product includes refuge that is interspersed within the field by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed. **The seed mix refuge option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ satisfies the refuge requirements in all regions other than in cotton growing regions where corn earworm is a significant pest as defined below.**

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

Additional refuge requirements in cotton-growing regions where corn earworm is a significant pest

In cotton-growing regions where corn earworm is a significant pest, as defined below, MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)	*Ostrinia nubilalis*
Southwestern corn borer (SWCB)	*Diatraea grandiosella*
Southern cornstalk borer (SCSB)	*Diatraea crambidoides*
Corn earworm (CEW)	*Helicoverpa zea*
Fall armyworm (FAW)	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Lesser corn stalk borer	*Elasmopalpus lignosellus*
Sugarcane borer (SCB)	*Diatraea saccharalis*
Western bean cutworm (WBC)	*Richia albicosta*
Black cutworm	*Agrotis ipsilon*
Western corn rootworm (WCRW)	*Diabrotica virgifera virgifera*
Northern corn rootworm (NCRW)	*Diabrotica barberi*
Mexican corn rootworm (MCRW)	*Diabrotica virgifera zeae*

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete™ is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: __/__/__

Public Participation for EPA-HQ-OPP-2011-0362 Pesticide Product; Registration Issuances for PIP Seed Blend

Anthia Peters to: Mike Mendelsohn, Robert Forrest, Kimberly Smith, Earl Ingram

04/08/2011 04:10 PM

Cc: Latasha White

The documents for EPA-HQ-OPP-2011-0362 (BRAD) Pesticide Product; Registration Issuances for PIP Seed Blend are now available on Regulations.gov

Anthia C. Peters
Office of Pesticides Programs
Docket Manager
ASRC Management Services
(703) 305-0032

DRAFT

Monsanto

BPPD has reviewed the information provided regarding the manufacturing process in Monsanto owned facilities and concludes that:

- The seed weighing technology should guarantee high accuracy around the determined target (mean weight or mean percentage) with very low expected variance provided that all of Monsanto's manufacturing plants maintain and follow the same procedures;

- The seed mixing technology will be set to satisfy growers expectation of uniformity but some degree of clumping of refuge seed may be possible. BPPD does not expect clumping of refuge plants in the field to impact IRM for ECB and SWCB (see BPPD 2011) because of very little expected asymmetrical movement between the two plant types (Bt and non-Bt) for both species as supported by Onstad and Gould (1998);

- Bt and refuge seed will be colored differently when seed blends are mixed in Monsanto owned manufacturing plants. Monsanto is also encouraging its seed company licensees to color the Bt and refuge seed differently. Coloring the two types of seed differently will provide an additional affirmation that the product is in fact a seed blend. It will also allow the applicant to more easily test for germination of refuge seed (to assure the 5% refuge is still guaranteed);

Monsanto has submitted additional information and a generic standard operating procedure to guarantee the same accuracy and quality assurance from independent seed dealers who are in charge of their own seed mixing process.Unfortunately, this information was very general and

Contains no CBI
Russ Swanson Monsanto
4/7/11

not specific enough for BPPD to ascertain that the target blend percentage will be assured in non-Monsanto facilities.

could license a QMP equivalent to outlined by USDA PVP

SmartStax RIB
SCHNEIDER, RUSSELL P [AG/1920]

to:
Mike Mendelsohn
04/08/2011 01:59 PM
Show Details

Only submissions made to EPA in support of the SmartStax RIB petition which were PR Notice 86-5 compliant and/or contained data are considered as Confidential Business Information by Monsanto.

Dr. Russell P. Schneider
Senior Director, Regulatory Affairs and Policy
Monsanto Company
1300 I St., NW
Suite 450 East
Washington, DC 20005
202/383-2866

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration ☐ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
File Symbol 524-XXX	Sheryl Reilly	☒ None ☐ Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete	PM # 92	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167
☐ Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application.
☒ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture.

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container	Various	☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Russell P. Schneider, Ph.D.	Senior Director, Regulatory Affairs and Policy	(202) 383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title
J. Austin Burns	Regulatory Affairs Manager
4. Typed Name: J. Austin Burns, Ph.D. Tel. (314) 694-6514	5. Date: April 6, 2011

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UNIT) STATES ENVIRONMENTAL PR' 'ECTION AGENCY
401 M Street, S. W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 (314) 694-6514	EPA Registration Number / File Symbol: 524-XXX
Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7	Date: April 6, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ (Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature	Date	Typed or Printed Name and Title
J. Austin Burns	April 6, 2011	J. Austin Burns Regulatory Affairs Manager

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Form Approved OMB No. 2070-0060

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

DATA MATRIX

Date: April 6, 2011	EPA Reg. No./File Symbol: 524-XXX	Page 1 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
NA	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture		Monsanto Company	OWN	Administrative This Application
NA	Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7		Monsanto Company	OWN	Supporting Data This Application
NA	The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn		Monsanto Company	OWN	Benefits This Application

Signature	Name and Title	Date
J. Austin Burns	J. Austin Burns, Ph.D. Regulatory Affairs Manager	April 6, 2011

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Washington, D.C. 20460

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DATA MATRIX

Date: April 6, 2011	EPA Reg. No./File Symbol: 524-XXX	Page 2 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS- Ø15Ø7 × MON- 88Ø17-3× DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Monsanto Company	OWN	Administrative
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization

Signature	Name and Title	Date
J. Burns	J. Austin Burns, Ph.D. Regulatory Affairs Manager	April 6, 2011

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Public File Copy

Revised GENSS RIB Complete EPA label - revision
BURNS, J AUSTIN [AG/1000]
to:
Mike Mendelsohn
04/06/2011 06:08 PM
Cc:
"SCHNEIDER, RUSSELL P [AG/1920]"
Show Details

1 Attachment

Revised GENSS RIB Complete label 4-6-2011 v2.pdf

<<Revised GENSS RIB Complete label 4-6-2011 v2.pdf>>

Mr. Mendelsohn. I am attaching a second version of the revised GENSS RIB Complete label with more consistent product naming throughout the document. I apologize for any inconvenience. Please refer to this version 2, and ignore the earlier version in my email from 2:08 PM.

As mentioned in my previous note, Monsanto utilizes an IRM/Grower guide, in addition to the bag-tag, that growers refer to for IRM instructions and conditions. Language requirements for both the bag/bag-tag and the IRM/Grower Guide are addressed in this revised label. In particular, the details of refuge requirements per states/counties are addressed in the Grower Guide. Our preference is to maintain this format (the bag-tags provide basic information and refer to the greater details in the grower guide). This provides a consistent location for guidance to growers across our Bt products, and works within the inherent space limitations on the bag-tags. Some differences in communication tools exist between Bt corn technology providers who may not utilize Grower Guides, and thus would need to include all the specific state/county information using very small font on the bag-tags. Monsanto prefers flexibility in our approach as this provides the most clarity to growers.

I hope this proposed approach between the bag/tag and the IRM/Grower Guide will satisfy your needs, and we provide language for both documents (bag/bag-tags and the IRM/Grow Guide) in the attached draft label. If this proposal is still a concern, I hope this format will be possible for the projected 2011 season (bag tags already printed), and if more significant changes are needed to the bag-tag, those could be made for the 2012 season.

Regards,

Regards,

Austin Burns, Monsanto

314-694-6514

From: BURNS, J AUSTIN [AG/1000]
Sent: Wednesday, April 06, 2011 2:08 PM
To: 'mendelsohn.mike@epa.gov'
Cc: SCHNEIDER, RUSSELL P [AG/1920]
Subject: Revised GENSS RIB Complete EPA label and Forms
Importance: High

Mr. Mendelsohn, please see the revised draft EPA label and application forms to reflect the changes you requested this morning. Please note, a portion of this label lists required language for the [Bag or Bag-Tag], and a second portion of the label refers to language to be included in the [IRM/Grower Guide]. Because the IRM/Grower Guide will contain many details for geographical IRM conditions, lists of states & county details, as well as a map and other graphical depictions, that document is the key piece information growers obtain such information. I hope this proposed approach between the bag/tag and the IRM/Grower Guide will satisfy your needs, and/or will be possible for the projected 2011 season (tags already printed), and more significant changes to the tag if necessary could be made for the 2012 season. Please don't hesitate to call if we should discuss further:

Regards,

Austin Burns, Monsanto

314-694-6514

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S. W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:	EPA Registration Number / File Symbol:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 (314) 694-6514	524-XXX
Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, CrytF1 Cry3Bb1, Cry34Abt and Cry35Abt Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHPt7662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7	Date: April 6, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-in response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-in response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature	Date	Typed or Printed Name and Title
J. Austin	April 6, 2011	J. Austin Burns Regulatory Affairs Manager

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EPA

United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
File Symbol 524-XXX	Sheryl Reilly	☒ None ☐ Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete	PM # 92	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167
☐ Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application.
☒ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cryl A.105, Cry2Ab2, CrylF, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture.

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container	Various	☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Russell P. Schneider, Ph.D.	Senior Director, Regulatory Affairs and Policy	(202) 383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title
	Regulatory Affairs Manager
4. Typed Name J. Austin Burns, Ph.D. Tel. (314) 694-6514	5. Date April 6, 2011

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Form Approved OMB No. 2070-0060

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401 M Street, S.W.
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DATA MATRIX

Date: April 6, 2011	EPA Reg. No./File Symbol: 524-XXX	Page 1 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete	

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
NA	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture		Monsanto Company	OWN	Administrative This Application
NA	Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7		Monsanto Company	OWN	Supporting Data This Application
NA	The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn		Monsanto Company	OWN	Benefits This Application

Signature	Name and Title	Date
J. Aus	J. Austin Burns, Ph.D. Regulatory Affairs Manager	April 6, 2011

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DATA MATRIX

Date: April 6, 2011	EPA Reg. No./File Symbol: 524-XXX	Page 2 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7 RIB Complete	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Monsanto Company	OWN	Administrative
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization

Signature	Name and Title	Date
J. Austin Burns	J. Austin Burns, Ph.D. Regulatory Affairs Manager	April 6, 2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Revised GENSS RIB Complete EPA label and Forms
BURNS, J AUSTIN [AG/1000]
to:
Mike Mendelsohn
04/06/2011 03:08 PM
Cc:
"SCHNEIDER, RUSSELL P [AG/1920]"
Show Details

2 Attachments

Revised GENSS RIB Complete EPA forms 4-6-2011.PDF Revised GENSS RIB Complete EPA label 4-6-2011.pdf

Mr. Mendelsohn, please see the revised draft EPA label and application forms to reflect the changes you requested this morning. Please note, a portion of this label lists required language for the [Bag or Bag-Tag[, and a second portion of the label refers to language to be included in the [IRM/Grower Guide]. Because the IRM/Grower Guide will contain many details for geographical IRM conditions, lists of states & county details, as well as a map and other graphical depictions, that document is the key piece information growers obtain such information. I hope this proposed approach between the bag/tag and the IRM/Grower Guide will satisfy your needs, and/or will be possible for the projected 2011 season (tags already printed), and more significant changes to the tag if necessary could be made for the 2012 season. Please don't hesitate to call if we should discuss further:

Regards,
Austin Burns, Monsanto
314-694-6514

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 29, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

RUSSELL P. SCHNEIDER
MONSANTO COMPANY
MONSANTO COMPANY
1300 I STREET, NW, SUITE 450 EAST
WASHINGTON, DC 20005-

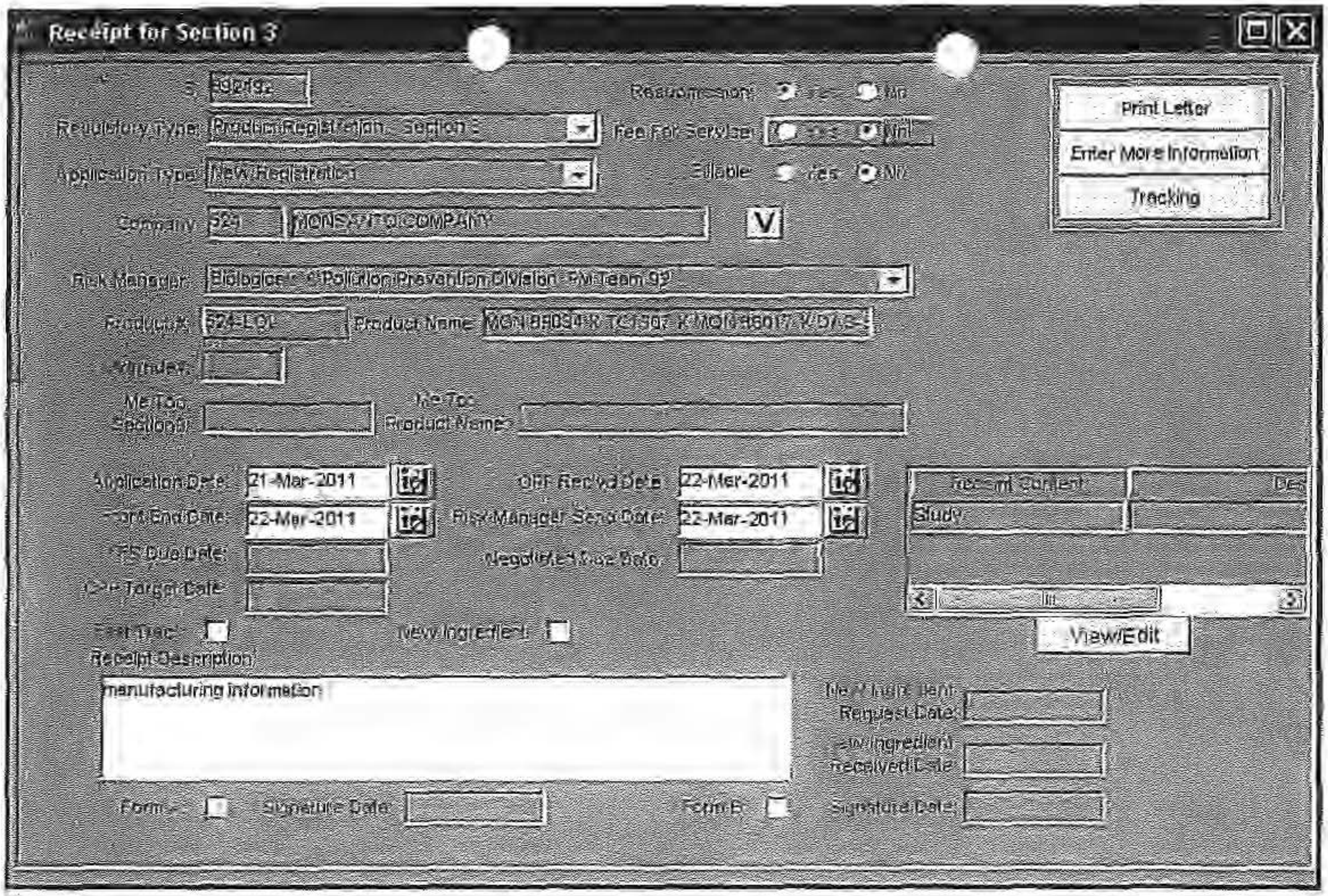
Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 22-MAR-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studes, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected Study [01]:

* Judging from the pagination of the study, pages **36-38** were omitted from the submitted copy.
* Your Statement of No Data Confidentiality Claims is contradicted by the markings on pages **1-35** of the study. If you do not intend to make Supplemental Claims of Data Confidentiality you can explicitly override these markings when you resubmit this study.


Receipt for Section 3
Resubmission: Yes No
Print Letter
Enter More Information
Tracking
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 524 MONSANTO COMPANY
Risk Manager: Biological & Pollution Prevention Division - PM Team 92
Product #: 524-LGL
Product Name:
Me Too Section:
Me Too Product Name:
Application Date: 21-Mar-2011
OPP Rec'vd Date: 22-Mar-2011
Front End Date: 22-Mar-2011
Risk Manager Send Date: 22-Mar-2011
PRIA Due Date:
Negotiated Due Date:
Receipt Content
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
manufacturing information
New Ingredient Request Date:
New Ingredient Received Date:
Signature Date:
Form B:
Signature Date:

MONSANTO
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Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, Missouri 63167
http://www.monsanto.com

March 21, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

Subject: Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures; EPA File Symbol 524-LOL

Dear Dr. Reilly:

Pursuant to the SmartStax® RIB registration request currently pending with the Agency, Monsanto hereby submits manufacturing information pertinent to both Monsanto (DeKalb) and a Monsanto licensee (Wyffels). Accompanying this letter are four manufacturing Standard Operating Procedures (SOPs) for your review. These SOPs describe the blending process for a seed mix of 95% SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) with 5% non-Bt seed.

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	A
Administrative Materials for Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures	A
Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures	B

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6425.

Sincerely,

Jeffrey T. Bookout, M.S.
Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD
Dr. Alan Reynolds, EPA BPPD
Dr. Russell P. Schneider, Monsanto Company
Mr. Daniel J. Jenkins, Monsanto Company

MONSANTO

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

EPA File Symbol 524-LOL

TRANSMITTAL DATE

March 21, 2011

MONSANTO REFERENCE No.

07-CR-192E-E3

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Administrative Materials for Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

MRID Number Administrative

Additional Information

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

MRID Number **Reject (01)**

Company Official: Jeffrey T. Bookout 3-21-11

Jeffrey T. Bookout, M.S. Date
Regulatory Affairs Manager
(314) 694-6425

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Senior Director, Regulatory Affairs and Policy
Washington D.C.
(202) 383-2866

MONSANTO
imagine

MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ST. LOUIS, MISSOURI 63167
http://www.monsanto.com

March 21, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

Subject: Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures; EPA File Symbol 524-LOL

Dear Dr. Reilly:

Pursuant to the SmartStax® RIB registration request currently pending with the Agency, Monsanto hereby submits manufacturing information pertinent to both Monsanto (DeKalb) and a Monsanto licensee (Wyffels). Accompanying this letter are four manufacturing Standard Operating Procedures (SOPs) for your review. These SOPs describe the blending process for a seed mix of 95% SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) with 5% non-Bt seed.

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Documents accompanying this letter:

Document	Category
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Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures	B

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6425.

Sincerely,

Jeffrey T. Bookout, M.S.
Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD
Dr. Alan Reynolds, EPA BPPD
Dr. Russell P. Schneider, Monsanto Company
Mr. Daniel J. Jenkins, Monsanto Company

MONSANTO

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

EPA File Symbol 524-LOL

TRANSMITTAL DATE

March 21, 2011

MONSANTO REFERENCE No.

07-CR-192E-E3

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Administrative Materials for Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

MRID Number Administrative

Additional Information

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

MRID Number **Reject (01)**

Company Official: Jeffrey T. Bookout 3-21-11

Jeffrey T. Bookout, M.S. Date
Regulatory Affairs Manager
(314) 694-6425

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Senior Director, Regulatory Affairs and Policy
Washington D.C.
(202) 383-2866

MONSANTO

Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

SmartStax®
EPA File Symbol 524-LOL

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide – Section I

Company/Product Number	2. EPA Product Manager	3. Proposed Classification
EPA File Symbol 524-LOL	Sheryl Reilly	☒ None ☐ Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	PM # 92	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167
☐ Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application.
☒ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures

Section – III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other
Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container	*(Specify)*

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
☐ Lithograph ☐ Other
☐ Paper glued
☐ Stenciled

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Dr. Russell P. Schneider	Senior Director, Regulatory Affairs and Policy	(202) 383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title	5. Date
Jeffrey T. Bookout	Regulatory Affairs Manager	March 21, 2011
4. Typed Name: Jeffrey T. Bookout Tel. (314) 694-6425		

Please read Instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95
EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S. W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of informalion is estimated to average t.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2 t37), U.S. Environmental Protection Agency, 40 t M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6425	EPA Registration Number / File Symbol:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	524-LOL
Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Cryl A.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7	Date: March 21, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7

NOTE: If your product is a t00% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the setective method), and have included with this form a completed list ol data requirements (the Oata Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

t certify that this application for registralion, this form for rereglstration, or this Data-Call-In response is supporled by all data submitted or cited in the application for registration, the form for reglstration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section t, thls application is supported by alt data In the Agency's files that (t) concern the properties or effects of this product or an identical or substantially similar product, one or more of the Ingredients In this product; and (2) Is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

t certify that for each exclusive use study cited in support of thls registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) t am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(t)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, If any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and wilt be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may Initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

t certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or Imprisonment of both under the applicable law.

Signature	Oate	Typed or Printed Name and Title
Jeffrey T. Bookout	March 21, 2011	Jeffrey T. Bookout, M.S. Regulatory Affairs Manager

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

DATA MATRIX

Date: March 21, 2011	EPA Reg. No./File Symbol: 524-LOL	Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures.		Monsanto Company	OWN	This Application
	Monsanto and Monsanto Licensee SmartStax® RIB Manufacturing Standard Operating Procedures.		Monsanto Company	OWN	Manufacturing Information

Signature	Name and Title	Date
Jeffrey T. Bookout	Jeffrey T. Bookout, M.S. Regulatory Affairs Manager	March 21, 2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: March 21, 2011	EPA Reg. No./File Symbol: 524-LOL	Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredients: *Bacillus thuringiensis* Cryt A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	[redacted]		Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Manufacturing Information

Signature	Name and Title	Date
Jeffrey T. Bookout	Jeffrey T. Bookout, M.S. Regulatory Affairs Manager	March 21, 2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Pages 292-325
Access to FIFRA health and safety data is restricted under FIFRA section 10(g)

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484234-00

MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005
PHONE (202) 383-2866
FAX (202) 789-1748
http://www.monsanto.com

March 18, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

Subject: Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the Scientific Advisory Panel, Dec 8-9, 2010 Regarding SmartStax® RIB; EPA File Symbol 524-LOL (Monsanto); EPA File Symbol 68467-RA (Dow AgroSciences)

Dear Dr. Reilly:

Thank you and your team for the opportunity to review our additional modeling results, presenting worst-case seed mix effects on heterozygous fitness, relative to a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on March 15, 2011. Accompanying this letter is a document reviewing the conservative modeling results discussed in the March 15, 2011 meeting, as well as our response to the December 8-9, 2010 Scientific Advisory Panel's concerns.

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	A
Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010	A
Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010	B

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.
Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD
Dr. Alan Reynolds, EPA BPPD
Dr. Russell P. Schneider, Monsanto Company
Dr. Nicholas Storer, Dow AgroSciences

MONSANTO

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010

EPA File Symbol 524-LOL

TRANSMITTAL DATE

March 18, 2011

MONSANTO REFERENCE No.

07-CR-192E-E2

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010

MRID Number _____

Additional Information

Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010

MRID Number 48423401

Company Official: _____ 3-18-2011

J. Austin Burns, Ph.D. Date
Regulatory Affairs Manager
(314) 694-6514

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.
Senior Director, Regulatory Affairs and Policy
Washington D.C.
(202) 383-2866

MONSANTO

Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010

SmartStax®
EPA File Symbol 524-LOL